The Lisbeth Hockey Community Nursing Research Training Fellowship 2008

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We acknowledge the important contribution that our ex-colleague Professor Hazel Watson made when developing the original proposal for this study, prior to her retirement in 2009.

We would also like to thank the people with stroke, and the health and social care professionals who participated in the Advisory Group.

Executive Summary

Background

Stroke is the most common cause of adult disability in the UK; the incidence is particularly high in Scotland, with more than 12,000 new cases per year. Stroke recurs in approximately 25% of patients and may result in death or an increased risk of disability or institutionalisation. Stroke is associated with a disadvantaged socio-economic profile and lifestyle behaviours which include smoking, unhealthy diet, excessive alcohol consumption and lack of exercise. Crucially, these factors are amenable to change by means of pharmacotherapy and/or the delivery of lifestyle interventions. While the provision of lifestyle interventions has the potential to improve health outcomes and reduce the extension of disability, there is currently a dearth of research in this area.

Estimates suggest that 80% of stroke survivors are living in the community, with approximately 50% of all stroke patients receiving district nursing care. It is therefore important that any intervention aimed at preventing stroke recurrence should be based in the community/primary care setting where it is known that the majority of contacts with health care personnel occur. Nurses based in the community/primary care setting are ideally placed to be part of the team that delivers such an intervention.

Recognising the need to develop an effective lifestyle intervention that has the potential to prevent stroke recurrence, we have developed a programme of research to address this gap. Our approach follows the Medical Research Council's recommendations for the development and evaluation of complex healthcare interventions. This framework describes a phased approach, which aims to improve the identification and utilisation of appropriate research methods, and to improve understanding of what constitutes an effective intervention in a particular context.

The development phase requires the gathering and synthesising of evidence with which to inform the content, design and delivery mode of a community based family-centred, secondary prevention intervention. Also during this phase, appropriate theoretical approaches are identified and developed. Prior to the inception of the Training Fellowship, two research studies were undertaken as part of the developmental phase of our research, a survey of stroke nurse practice regarding secondary prevention of stroke and a focus group study that explored the lifestyle beliefs and lifestyle behaviour of patients and family members following stroke.

At this stage in the development phase of our programme of stroke secondary prevention research, in December 2008, the Lisbeth Hockey Community Nursing Research Training Fellow joined the research team.

Aims

The Research Training Fellowship aimed to provide opportunities for the development of a range of transferable research skills by enabling a community nurse, the Research Training Fellow, to contribute to the development of a community-based model for a family-centred lifestyle intervention for people who have had a stroke and their family members. Three objectives were described, namely to:

1. Contribute to the development of the intervention development,
2. Enhance stakeholder involvement, and to
3. Contribute to proposal development.

Intervention development

The principal objective was for the fellow to contribute to the development of a community-based model for an evidence-based, family-centred lifestyle intervention for people who have had a stroke and their family members. Research activities undertaken in fulfillment of this objective included the identification and synthesis of evidence. The principal synthesis activity was the conduct of a systematic review of the literature.

Systematic review

As part of the research team, who are members of the Scottish Centre for Evidence Based Care of Older People, the Training Fellow undertook a systematic review entitled, *A systematic review of the effectiveness of secondary prevention lifestyle interventions designed to change lifestyle behaviour following stroke.* The review will be published in the JBI Library of Systematic Reviews. Key review findings indicate that lifestyle interventions have the potential to improve behavioural outcomes following stroke.

Identifying and developing the theory

The intervention development stage of our programme of research also included the identification and development of appropriate theoretical approaches with which to underpin our developmental work and the design and delivery of a secondary prevention intervention.

Acknowledging the complex psychological processes associated with lifestyle behaviour/behaviour change, the Theory of Planned Behaviour (TPB) was selected to inform our research. TPB describes and explains behaviour and behaviour change as determined by intentions to engage/not to engage in specific behaviours e.g. smoking. Intentions are informed by attitudes, motivation and perceived behavioural control; factors embedded in/influenced by intersubjective relationships within the family. Similarly, recognising the importance of the family construct, the Calgary Family Assessment/Intervention model (CFAM/CFIM) was selected to complement the TPB. CFAM/CFIM is a family systems theory centred on the family's reciprocal relationships, including those with external agencies e.g. healthcare practitioners. CFAM/CFIM enables the family to understand its internal processes and how it 'works' as family by encouraging introspection and collaboration. It enables practitioners to take into account the uniqueness of families, their processes and needs, and facilitates an understanding of the process of an intervention rather than simply its outcomes.

Stakeholder involvement

All elements of this programme of stroke secondary prevention research have a strong service user focus, as we believe that it is essential that patients and family members' are involved in the development and the evaluation of healthcare interventions. The second objective of the fellowship was to enhance and facilitate lay representation on the Research Advisory Group, and to broaden the consultation process by seeking to meet with clinicians and managers to ascertain their views and priorities in relation to the design and delivery of stroke secondary prevention services.

Enhanced lay representation was secured by establishing contact with pre-existing networks, conducting recruitment visits to voluntary sector organisations, developing lay versions of project information, and organising a pre-Advisory Group meeting for lay representatives to facilitate their meaningful participation in the full Research Advisory Group meeting.

In 2009/2010, we broaden our consultation activities to include individual community-based clinicians and managers actively involved in developing and delivering stroke services. To enhance our understanding of their various roles and perspectives, and the relevance of the CFAM/CFIM to secondary prevention of stroke practice, the research fellow secured shadowing opportunities with stroke nurses in three Scottish health boards, working in a range of clinical settings.

Proposal development

The third objective specified that the Training Fellow would contribute to the development of a research proposal for a pilot study of the intervention in a community setting. However, our programme of secondary prevention research had not progressed to this stage before the completion of the fellowship. Nevertheless, the Training Fellow contributed to the development of the systematic review protocol, which required acquiring and using skills that mirror those required for the development of a research proposal.

Future plans

Members of the research team have secured funding from the QNIS for a mixed methods study, The Contribution of Perceived Stress in Stroke (COPerSS). COPerSS aims to explore perceptions of psychological stress in people with a diagnosis of transient ischaemic attack/minor stroke. Perceived stress is an emerging risk factor for stroke, which we aim to address in our secondary prevention intervention.

In autumn 2011, we plan to move onto the next stage of our programme of secondary prevention research i.e. intervention modelling, development and feasibility testing.

Conclusion

The Lisbeth Hockey Community Nursing Research Training Fellowship 2008 represents a key evidence gathering and evidence synthesising element of our programme of secondary prevention research. The fellowship enabled a community nurse to make a valuable and ongoing contribution to this important programme of research as well as honing and acquiring a range of transferable research kills, thus enhancing community nursing research capacity. The research fellow will continue to contribute to the work as a member of the Research Advisory Group.

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Project Management[1]

Research Team

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Dr Susan Kerr, Reader, School of Health/IAHR, GCU

Dr Dorothy Ferguson, Head of Learning, Teaching & Quality, School of Health, GCU

Lorna Dunipace, Head of Health and Community Care, East Glasgow CHP, Bridgeton, Glasgow

Research Advisory Group

Gill Bowler, Lay representative, Edinburgh

Peter Callaghan, Lay representative, Glasgow

John Dennis, Long-term Conditions Stroke Review Project Manager, Glasgow

Claire Diamond, Stroke Support Nurse, North Ayrshire

Graham Ellis, Consultant, Medicine for the Elderly, Lanarkshire

Maddy Halliday, Director Scotland, the Stroke Association, Edinburgh

Catriona Jennings, MyAction Director of Nursing, Imperial College, London

Jacklyn Jones, Lecturer in Dietetics, Queen Margaret University, Edinburgh

Gillian Mead, Geriatrician, Clinical Senior Lecturer, University of Edinburgh

Gillian Paton, Senior Speech & Language Therapist, Royal Alexandra Hospital

Julia Quickfall, Director, Queen's Nursing Institute, Scotland, Edinburgh

Jeanette Smith, Lay representative, Glasgow

Ellen Townend, Chartered Health Psychologist, NHS Fife

Tracie Wotherspoon, Stroke Nurse Specialist, NHS Greater Glasgow & Clyde

[1] Note: The initial proposal for funding was submitted in partnership with HealthQWest, one of three NMAHP research consortia in Scotland. Funding for the three consortia ceased in August 2010. Health-related research at Glasgow Caledonian University is now located within the Institute for Applied Health Research (http://www.gcu.ac.uk/iahr/).

1. Background

Stroke is the most common cause of adult disability in the UK; the incidence is particularly high in Scotland, with approximately 13,000 new cases per year (Scottish Health Statistics 2006). Identified recently by the Scottish Government as one of the four National Clinical Priorities (Scottish Government 2007), stroke is associated with a disadvantaged socio-economic profile and lifestyle behaviours which include smoking, unhealthy diet, excessive alcohol consumption and lack of exercise (Redfern et al 2006; O'Donnell et al 2010).

Stroke recurs in approximately 25% of patients and this may result in death or an increased risk of disability or institutionalisation (Hankey et al 2007). Ten factors are associated with 90% risk of stroke i.e. hypertension, smoking, waist-to-hip ratio, diet risk score, physical inactivity, diabetes mellitus, alcohol intake, psychosocial stress, depression and cardiac causes (O'Donnell et al 2010). Many of these are lifestyle behaviours/associated with lifestyle behaviours, and are amenable to change (Redfern et al 2006). Therefore, targeted primary/secondary prevention interventions have the potential to substantially reduce the burden of stroke. In terms of pharmacotherapy, rates of treatment with combination therapy (i.e. antiplatelet, antihypertensive and statin) are low (Ramsay et al 2007), and this is compounded by low rates of medication adherence (O'Carroll et al 2010). Therefore, secondary prevention interventions should be multimodal i.e. include prescription of selective medication in conjunction with active provision of lifestyle information and education regarding medication adherence, using behaviour change techniques (Sacco et al 2006). Such interventions should be informed by behaviour change theory, and understanding of the barriers to medication adherence, and tailored to the needs/priorities of individuals and their families (Scottish Intercollegiate Guidelines Network, 2008). Interventions should be initiated in hospital, and followed up in primary care (Scottish Executive 2002; NHS Education for Scotland 2006). However, contemporary secondary prevention care is known to be suboptimal (Ramsay et al 2007; O'Carroll et al 2010).

Recognising the need to develop an effective lifestyle intervention that has the potential to prevent stroke recurrence, an established team of researchers, led by Dr Maggie Lawrence, has developed a programme of research to address this gap. A family-centred[2] intervention is proposed. The intervention will be multimodal and will address lifestyle risk factors for recurrent stroke i.e. smoking, diet, physical inactivity, and alcohol consumption.

[2] Family is defined as 'a self-identified group of two or more individuals who consider themselves to be a family' (Whall, 1986).

1.1 Research Approach

Our approach to this programme of research follows the recommendations contained within the Medical Research Framework (MRC) for the development and evaluation of complex healthcare interventions (MRC 2000 & 2008). This framework describes the phased approach advocated by the MRC in order to improve the identification and utilisation of appropriate research methods, and to improve understanding of what constitutes an effective intervention in a particular context. Often, this is an iterative process, which incorporates both qualitative and quantitative research approaches (MRC 2008) (Appendix 1). In the first, or development phase, appropriate theoretical approaches are identified and developed and evidence is gathered and synthesised to form an evidence base which will inform the content, design and delivery mode of the proposed intervention.

The Theory of Planned Behaviour (TPB) (Ajzen 1991) was selected as the theoretical underpinning for our proposed programme of research, and three principal evidence gathering and synthesising activities, which would be undertaken as part of the developmental phase of our programme of stroke secondary prevention research, were described. Namely,

1. a survey of stroke nurse practice regarding secondary prevention of stroke (Lawrence et al 2009a & b),
2. a focus group study to explore the beliefs and perceptions of patients and family members regarding the provision of lifestyle information following stroke (Lawrence et al 2010), and
3. a systematic review of the effectiveness of secondary prevention lifestyle interventions designed to change lifestyle behaviour following stroke.

In 2007, we secured internal and external funding for activities one and two, as listed above. In 2008, we secured the Lisbeth Hockey Community Nursing Research Training Fellowship, the focus of which was on the conduct of a systematic review of the effectiveness of secondary prevention lifestyle interventions designed to change lifestyle behaviour following stroke. The review was undertaken in collaboration with the Scottish Centre for the Evidence Based Care of Older People, a collaborating centre of the Joanna Briggs Institute (JBI)[3], of which Dr Lawrence is a Depute Director.

[3] JBI, a globally recognised leader in evidence-based healthcare, offers a range of evidence-based resources, designed to enhance the provision of culturally sensitive, evidence-based healthcare in a range of settings (http://www.joannabriggs.edu.au/about/home.php).

2. Recruitment of the Training Fellow

This Lisbeth Hockey Community Nursing Research Training Fellowship 2008, was developed to provide a community nurse with the opportunity to join an established team of researchers working on a programme of secondary prevention stroke research.

We were fortunate to recruit Caroline McVey, an experienced public health nurse, to take up the Research Training Fellowship.

3. Aims and Objectives of the Research Training Fellowship

The Research Training Fellowship aimed to provide opportunities for the development of a range of transferable research skills by enabling a community nurse, the Research Training Fellow (RTF), to contribute to the development of a multimodal, family-centred lifestyle intervention for people who have had a stroke and their family members. It was proposed that this was to be achieved in the following ways:

1. **Intervention development:** the fellow would contribute to the development of a community-based model for an evidence-based, family-centred lifestyle intervention for people who have had a stroke and their family members.
2. **Stakeholder involvement:** the fellow would explore the feasibility of the intervention model with selected stakeholders, such as families that include a member who has had a stroke, members of the multidisciplinary primary care team and stroke specialists.
3. **Proposal development:** the fellow would contribute to the development of a research proposal for a pilot study of the intervention in a community setting.

The outcomes of the training fellowship as they relate to these three activities are described below.

3.1 Intervention Development

The principal objective was for the RTF to contribute to the development of a community-based model for an evidence-based, family-centred lifestyle intervention for people who have had a stroke and their family members. The first stage of a research programme such as this includes identification and synthesis of the evidence that will inform the development of the proposed intervention, and the identification and development of an appropriate theoretical approach.

3.1.1 Evidence Synthesis

Evidence synthesis activities focused on the conduct of a systematic review of the literature. The original application to the QNIS proposed that we would conduct a critical review of the literature. However, as the research team are closely involved with the work of the Scottish Centre for Evidence Based Care of Older People, it was felt that conducting a systematic review of effectiveness, using JBI methodology and methods, would provide an enhanced learning opportunity for Caroline, as well as providing enhanced project outcomes. To contribute effectively to the systematic review process, Caroline was required to develop pre-existing research skills and acquire new research skills (see Appendix 2).

Caroline worked closely with the research team on the development of the protocol for a systematic review: *A systematic review of the effectiveness of secondary prevention lifestyle interventions designed to change lifestyle behaviour following stroke* (Lawrence et al 2009c). Caroline had a key role throughout the review process, being involved in the identification, retrieval and selection of the documents to be included in the review, and in the critical appraisal and data extraction processes. Caroline also prepared statistical data, developed evidence tables, and participated in the preparation of the final review report, which is reproduced in full in Appendix 3.

3.1.2 Identifying and Developing the Theory

To facilitate our understanding of the mechanisms that influence family-centred lifestyle behaviour change, it was necessary to identify and develop an appropriate theoretical framework that will inform our programme of family-centred secondary prevention research and facilitate our understanding of the processes of the proposed intervention rather than simply its outcomes.

As described above, in acknowledgment of the complexity of lifestyle behaviour/behaviour change a psychological approach, the Theory of Planned Behaviour (TPB) (Ajzen, 1991), had previously been selected to inform our research. TPB describes and explains behaviour and behaviour change as determined by intentions to engage/not to engage in specific behaviours e.g. smoking. Intentions are informed by attitudes, motivation and perceived behavioural control; factors embedded in/influenced by intersubjective relationships within the family.

Similarly, recognising the importance of the family construct, the Calgary Family Assessment/Intervention model (CFAM/CFIM) (Wright and Leahey, 2005) was selected to complement the TPB. CFAM/CFIM, a family systems theory focuses on the family's reciprocal relationships, including those with external agencies such as healthcare practitioners. CFAM/CFIM enables practitioners to take into account the

uniqueness of individual families. It encourages introspection and collaboration between family members, and aims to improve family function by enabling families to understand their internal processes and how they 'work' as a family unit, and how to identify their own strengths and needs.

During the term of the fellowship, Caroline initiated work on the development of a comprehensive model, which demonstrates how these two models may be combined, in terms of theoretical application to the research process and in terms of practical application in community-based practice. The research team, in consultation with the Research Advisory Group, of which Caroline is a member, will further refine this theoretical model in subsequent stages of the research programme.

3.2 Stakeholder Involvement

The second Fellowship objective aimed to improve stakeholder involvement in our proposed programme of research by enhancing and facilitating lay representation on the Research Advisory Group, and by consulting widely with clinicians and managers.

3.2.1 Enhancing Lay Representation

Caroline used a range of methods and approaches which aimed to secure enhanced lay representation on the Research Advisory Group. Her activities included:

- Establishing contact with pre-existing networks
- Conducting recruitment visits to voluntary sector organisations
- Developing lay versions of project information, and
- Organising a pre-Advisory Group meeting for lay representatives to facilitate their meaningful participation in the full Advisory Group meeting

3.2.2 Consulting with the Research Advisory Group

In June 2009, we consulted with the Advisory Group regarding the development of the intervention. The research team presented an overview of the research activity to date, and preliminary evidence summaries derived from the early stages of the systemic review process. Caroline then presented an overview of the family systems nursing model, the CFAM/CFIM. This was followed by lively discussion and debate, which was summarised and incorporated into the evidence synthesis process.

Important lessons were learnt as a result of this consultation meeting including issues regarding the facilitation of the meaningful involvement of lay representatives in an advisory group comprising healthcare professionals and representatives from voluntary sector organisations. To ensure that lay representatives are able to participate fully, detailed preparation, easy-access information, and service user support are required.

3.2.3 Consulting with Key Stakeholders

In 2009/2010, we broaden our consultation activities to include individual community-based clinicians and managers actively involved in developing and delivering stroke services.

Caroline, along with other members of the research team, met with Lorna Dunipace, Head of Service, East Glasgow CHCP who agreed to facilitate access to local groups, including the Rehabilitation Enablement and the Health Improvement planning groups. The research team will be able to take advantage of this opportunity to consult with these groups and thus prepare the way for piloting an intervention/s in east Glasgow.

Caroline also contributed to meetings that were held with Stroke Managed Clinical Network (MCN) Managers in Glasgow and in Ayrshire and Arran, both of whom provided useful insights into the structure of stroke service provision in their MCN areas and nationally. Both MCN managers have offered to support our research and/or collaborate in future activities that relate to this programme of research.

To enhance our understanding of the various roles of stroke nurses working in liaison roles and in community settings, and to gain some insight into the relevance of the Calgary Family Assessment/Intervention Model (CFAM/CFIM) to secondary prevention of stroke practice, Caroline obtained permission to ‘shadow’ three nurses whose roles involved delivering secondary prevention interventions. Caroline secured shadowing opportunities with Stroke Liaison Nurses in NHS Ayrshire and Arran and NHS Greater Glasgow and Clyde, and with a Stroke Nurse Consultant in NHS Lanarkshire, and was able to observe practice on a ward, in patients’ homes and in a TIA/Stroke clinic.

Caroline reflected on the services delivered by these clinicians in the light of the three domains of assessment as described in CFA/IM i.e. structural, developmental and functional assessment, and in terms of behaviour change theory.

3.2.3.1 Structural Assessment

Structural assessment involves assessing who is in the family (internal structure), family connections with people outside of the family (external structure), and the

family's context (Wright and Leahey, 2005). It was observed that clinicians routinely assessed internal family structure and recorded the information in the notes. External structure was assessed, where appropriate; however, the wider family context was less likely to be addressed.

3.2.3.2 Developmental Assessment

Assessment of the developmental life cycle of the family involves assessment of the family's construction of its development over time, in particular the sequential phases of old and new generations (Wright and Leahey, 2005). The clinicians did not formally assess developmental aspects; however, on several occasions informal assessment was made. For example, one nurse verbally assessed the emotional needs of younger family members who were adjusting to changes in the family's development as their parents moved towards the 'end of life' stage, but did not record this assessment in the case notes.

3.2.3.3 Functional Assessment

Functional assessment is concerned with how individuals actually behave in relation to one another in terms of instrumental function and expressive function. This type of assessment was not conducted routinely. However, in terms of instrumental function, on occasion the nurses did ask questions regarding the roles and responsibilities of the family members, and activities of daily living. The nurses encouraged greater independence in families where the patient had assumed a dependent role that was reinforced by the family carer's behaviour. Similarly, informal assessments of expressive functioning i.e. assessment of a family's problem solving behaviour and their verbal/non-verbal communication were made, although not routinely.

3.2.3.4 Lifestyle Risk Factor Behaviour Change

Caroline observed assessments of lifestyle risk factor behaviours i.e. tobacco use, unhealthy diet, physical inactivity and excessive alcohol consumption. The nurses also assessed, although not routinely, individual's willingness to make positive changes to their lifestyle. Following assessment, generic advice and information leaflets were dispensed. No referrals were made to specialist services, however, documentation regarding the lifestyle risk factor assessment and any associated recommendations was sent to the patient's GP.

The insights regarding secondary prevention provision gained from these shadowing opportunities will be incorporated into the developing evidence base that will inform the design of a secondary prevention intervention.

3.3 Proposal Development

The third objective specified that the training fellow would contribute to the development of a research proposal for a pilot study of the intervention in a community setting. However, our programme of secondary prevention research had not progressed to this stage before the completion of the fellowship. Nevertheless, Caroline contributed to the development of the systematic review protocol (Lawrence et al., 2009,), acquiring and using skills that mirror those required for the development of a research proposal. These transferable skills included:

- compiling an argument in support of the proposed research activity, which in this instance required a comprehensive understanding of the stroke secondary prevention literature
- gaining an understanding of systematic review methods
- acquiring advanced critical appraisal skills
- developing data collection (extraction) tools
- determining project timeframes
- developing academic writing skills
- demonstrating organisational skills
- working to deadlines
- responding to peer-review comments

4. Dissemination

Dissemination is an important aspect of the research process, which requires a strategic approach and an awareness of a range of dissemination mechanisms. As part of the research team, Caroline was able to gain valuable transferable research skills by engaging in a range of dissemination activities undertaken throughout the term of the fellowship, as detailed below.

4.1 Publications

- Lawrence M, Kerr S, McVey C., Godwin J., 2011. A systematic review of the effectiveness of secondary prevention lifestyle interventions designed to change lifestyle behaviour following stroke. *JBI Library of Systematic Reviews*, accepted for publication

- Lawrence M, McVey C, Kerr S, 2010. What is the evidence for using family based interventions to prevent stroke recurrence? *Nursing Times*, 106(11):22-25
- Lawrence M, Kerr S, McVey C, 2009. *A systematic review of the effectiveness of secondary prevention lifestyle interventions designed to change lifestyle behaviour following stroke.* [peer reviewed protocol]. JBI, Adelaide

In addition to the above, Caroline will contribute to the development of a paper reporting the results of the systematic review which will be submitted to an international, peer-reviewed journal such as 'The Lancet'.

4.2 Presentations to National and International Conferences

- Lawrence M, Kerr S, McVey C., 2010. Secondary prevention lifestyle interventions: what works? Results of a systematic review. [conference abstract] *International Journal of Stroke,* 5(supplement 3):6-7
- Lawrence M, McVey C, Kerr S., 2010. *A family-centred approach to the management of lifestyle risk factors for recurrent stroke.* [Symposium paper] International Nursing Research Conference, May 2010, Newcastle-upon-Tyne
- Lawrence M, McVey C., 2009. *The challenges and triumphs of carrying out a community-based project*. QNIS Research Fellows and Projects Forum, March 2009
- McVey C, Lawrence M, Kerr S, Ferguson D., 2009. *Secondary prevention of stroke.* [poster] QNIS Annual Conference, 2009

In addition to the above, Caroline made informal presentations to voluntary sector organisations in Edinburgh (Vocal) and in Glasgow (Differentstrokes).

5. Training

A stated aim of the fellowship was to provide the fellow with a range of experiences that would enable her to become an independent researcher. Recognising that Caroline had research skills attained during pre-registration and post-registration education and practice, we sought to offer Caroline opportunities to build on her pre-existing knowledge.

Following discussions with members of the research team, Caroline identified her research-related training and learning needs. Throughout the fellowship Caroline was encouraged to participate in a range of educational opportunities, including research modules, seminars and workshops (Appendix 2). In March 2010, Caroline completes the JBI accredited Comprehensive Systematic Review Training (three modules over five days), which enabled her to consolidate and extend her

systematic review skills. Caroline also had the opportunity to learn through the following general mechanisms:

- gaining insight into selected aspects of the work of the Improving Health and Wellbeing group/Individual, Family and Community Interventions research group
- networking with the wider community nursing academic team
- observation/participation in Research Team meetings
- shadowing researchers when, for example, developing a systematic review protocol
- contributing to the development of papers for publication
- attending research seminars
- accessing support from the Caledonian Graduate School

In her capacity as research training fellow, Caroline joined a team of experienced researchers, and as such had the opportunity to develop specific research skills:

- team working
- project-specific knowledge
- critical analysis skills
- extracting, analysing and presenting quantitative data
- evidence synthesis skills
- contributing to report writing
- recruiting Research Advisory Group members
- preparing project information sheets, in accessible formats
- contributing to the development of an appropriate theoretical model
- preparing and co-leading papers for presentation at national and international conferences
- preparing a poster for presentation at a national conference
- preparing and co-authoring a paper for publication in a nursing practice journal

- disseminating information regarding the Fellowship through conference presentations

6. Summary

Since 2007, we have been engaged in the development of a programme of health promotion research, which is concerned, with the secondary prevention of stroke. Uniquely this programme of work, developed in accordance with the MRC guidance, and informed by behaviour change theory and family systems theory, has adopted a community-based, family-centred approach to the development of a complex intervention. In preparation for undertaking intervention design and modelling, the first phase of our research has focused on identifying and developing the evidence base and identifying and developing an appropriate theoretical underpinning. Caroline McVey, the Research Training Fellow, joined the research team during this phase of the research. To enable Caroline to contribute to the development of the intervention, and in doing so acquire a range of transferable research skills, three project objectives were described i.e. evidence identification and synthesis, liaison with stakeholders and development of a funding proposal. All of these objectives were met and indeed surpassed during the course of the fellowship, enabling Caroline to make a valuable contribution to the evidence base that will inform the next phase of our programme of secondary prevention research i.e. intervention design and modelling. Following completion of the fellowship, Caroline has joined the Research Advisory Group, as a means of continuing her active involvement in the secondary prevention research programme.

7. Future Plans

Members of the research team have secured funding from the QNIS for a mixed methods study, The Contribution of Perceived Stress in Stroke (COPerSS). COPerSS aims to explore perceptions of psychological stress in people with a diagnosis of transient ischaemic attack/minor stroke. Perceived stress is an emerging risk factor for stroke, which we aim to address in our secondary prevention intervention.

In autumn 2011, we plan to move onto the next stage of our programme of secondary prevention research i.e. intervention modelling, development and feasibility testing.

8. Conclusion

The Lisbeth Hockey Community Nursing Research Training Fellowship 2008 represents a key evidence gathering and evidence synthesising element of our programme of secondary prevention research. The fellowship enabled a community nurse to make a valuable and ongoing contribution to this important programme of research as well as honing and acquiring a range of transferable research skills, thus enhancing community nursing research capacity. The Research Training Fellow will continue to contribute to the work as a member of the Research Advisory Group.

9. Financial report

The estimated project costs exceeded the limit of funds available from the Queen's Nursing Institute Scotland (£30k); therefore the School of Health, Glasgow Caledonian University, contributed an additional £3,158.00.

Item	Actual expenditure (£)
Travel	27
Stationery and postage	8
Advisory Group catering	61
Conference fees/accommodation/travel/subsistence	905
Printing report and executive summaries	100
Research Fellow Salary (incl NI & superannuation)	24,226
Salaries: mentoring support from project team	4,543
Research Fellow recruitment costs (Glasgow Herald)	3,288
Total spent	33,158
Monies from QNIS	30,000
Monies from GCU	3,158
Balance	0

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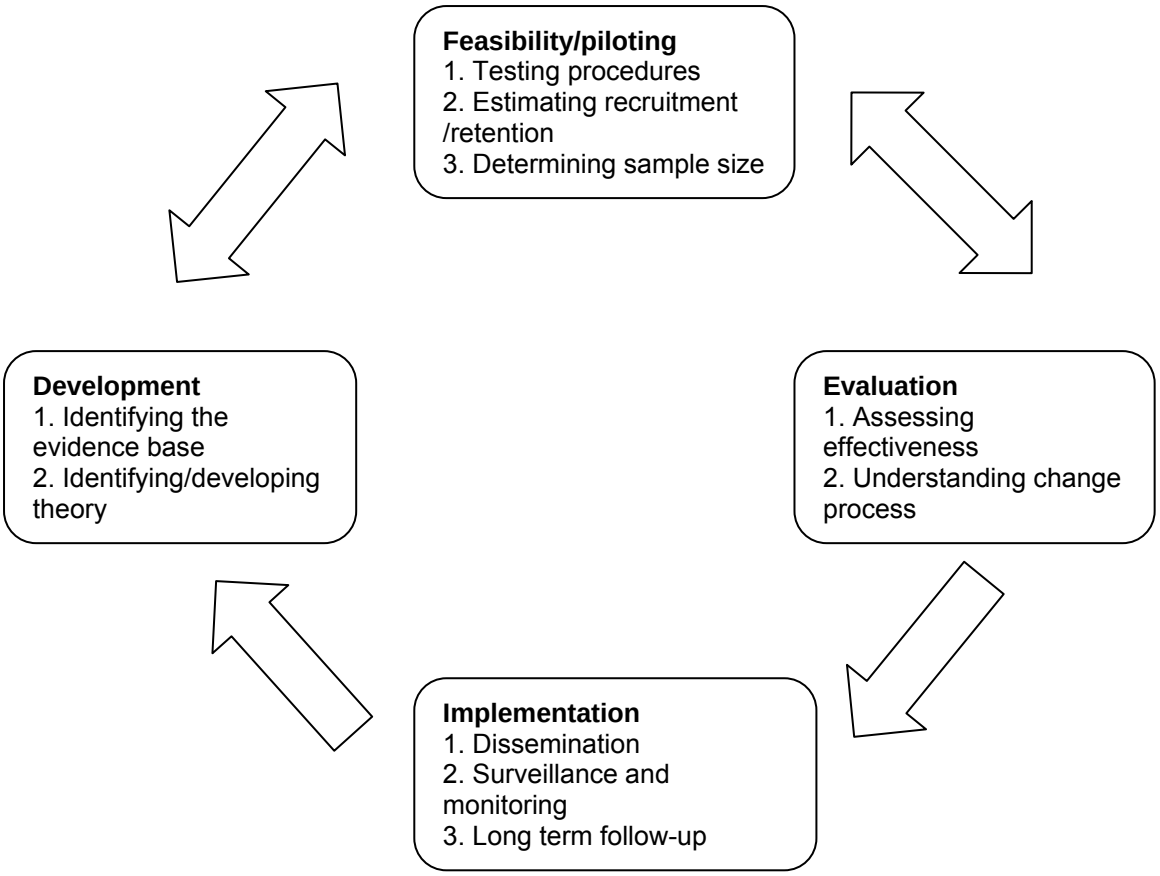
Appendices

Appendix 1: Key Elements of the Development and Evaluation Process: Medical Research Council's 'Framework for Development and Evaluation of RCTs for Complex Interventions to Improve Health' (2008)



Appendix 2: Training record

Topic	Learning Outcomes	Training Provider/Dates
Orientation Performance Annual Review	Performance Annual Review (PAR) GCU Graduate Centre	GCU Graduate Centre, 9.12.08; ½ day
Induction	Induction: Organisational Development. Introduction to GCU, different organisational departments, how they can be accessed and services available.	GCU, 8.1.09; full day
Aims & Objectives	Development of project timelines	Maggie Lawrence
Research Methods 'The Nature of Enquiry'	Research Methods 1: Workshop on the research process (paradigms), nature of the problem, simple research questions, qualitative versus quantitative. Questioning preconceived definitions of research. Contextualising boundary problems of research and relate these boundary problems to own field of enquiry. Be sensitive to the needs of different audiences, & purpose of research & authorship. Critically perceive and unpack the so called quality assurance mechanisms that exist in research communities today & what these implications mean for the research & for the researcher. Be able to contextualise the theory of knowledge in relation to own research work and practices.	GCU Graduate Centre, Dr Kevin Gran & Dr Peter Duncan 27.2.09 ½ day
Philosophies of Research 'Positivism & the black arts'	Research Methods 2: Looking at the positivistic approach, advantages and disadvantages. Questioning preconceived views and definitions of knowledge, power, politics & research. Contextualise the concepts of knowledge, power, politics & research problems to own field of own field of enquiry. Awareness of sensitivities to the needs of different research perspectives. Contextualise the theories & make sense of the implications of following particular research approaches in the overall research design.	GCU Graduate Centre, Dr Kevin Grant, Dr Peter Duncan, Prof. Hugh O'Donnell 27.3.09; ½ day
Methodologies: 'Plan of Attack'	Research Methods 3: Introduction to research methods; quantitative, qualitative and mixed research designs. Identifying relationships between theory and method and the appraisal of research design	GCU Graduate Centre, Dr Angus McFadyen, Dr John McKendrick, Dr Rosemary Whyte 21.4.09; ½ day

Topic	Learning Outcomes	Training Provider/Dates
Systematic review methods	Guidance from ML & self-directed learning re systematic review methods, database searches and retrieval of literature	Maggie Lawrence January/Feb 2009
Literature review and protocol development	Narrowing focus of literature searching to develop background for review protocol. Protocol development.	Maggie Lawrence February 2009
Systematic review methods	Development of systematic search strategy, familiarisation with a range of electronic bibliographic databases, bibliographic data entry, literature retrieval, screening papers for inclusion, quality appraisal, data extraction, liaison with authors requesting additional data, data entry	Maggie Lawrence March – June 2009
Systematic review methods	JBI Comprehensive Systematic Review Training Module 1: Introductory module Module 2: Non-experimental studies Module 3: Qualitative and textual studies	Scottish Centre for Evidence Based Care of Older People, March 2010
Bibliographic data management	Self directed learning using worksheets plus work shop re use of RefWorks	GCU Graduate Centre, Librarian, 10.2.09; ½ day
Statistics Intermediate Statistics	Self directed learning using workbooks under the guidance of Dr Gardner re use of statistical software packages, including Minitab, SPSS & Excel. Data summarisation, graphic and numeric, and inferential methods (hypothesis testing) for 2 sample designs. Data summarisation & hypothesis testing for one-way repeated measure designs. Parametric & nonparametric analyses.	GCU Graduate Centre, Dr Bill Gardner 14.1.09; full day

Topic	Learning Outcomes	Training Provider/Dates
Dissemination Communication Skills: Presentation	Overcoming apprehension of presentations: developing and exploring good presentation skills	GCU Organisational Development, 12.1.09; ½ day
Poster design	Self-directed learning re design of poster for QNIS conference. Background reading, awareness of appealing to a specific audience	GCU, research team February 2009
Presentation development	Collaborated on the development of conference papers	Maggie Lawrence
Presentation delivery	Presented an informal paper on challenges of being a research training fellow to the QNIS Fellows & Project Forum 2009	19.3.09; ½ day
	Co-presented a symposium paper at the RCN International Nursing Research Conference, 2010	12-13.05.10; 2 days
Development of project information sheets	Self-directed development for a project information sheet for dissemination to support groups to recruit lay representatives to advisory group	31.3.09
	Development of information leaflet as background information to project for people who have had a stroke.	12.5.09
Theory Background Reading	Self-directed background reading of CFAM, CFIM & Theory of Planned Behaviour and re family interventions.	March – June 2009
Recruitment of lay representatives Recruitment of lay representatives to project advisory group	Meeting with stroke support group members in Glasgow & Edinburgh for informal information session to raise awareness of the research & to recruit to advisory group.	January 2009 & May 2009 Maggie Lawrence & Caroline McVey

Topic	Learning Outcomes	Training Provider/Dates
Research project meetings Pre-advisory group meetings	Informative meeting on project and learning experiences of people who have had a stroke, which included people of all age groups. Meeting with Maggie Lawrence & Dr Susan Kerr to develop evidence summaries and other papers for the project advisory group meeting Preparation for advisory group meeting. Developing information leaflets that both professionals & individuals who have had a stroke	26th May 2009 ½ day Maggie Lawrence & Dr Susan Kerr Dr Susan Kerr & Maggie Lawrence 18.5.09 Maggie Lawrence 01.06.09, ½ day
Research Advisory Group meeting	Presented a paper re the theoretical underpinnings of the project and led a group discussion on intervention development	09.06.09

Appendix 3

A systematic review of the effectiveness of secondary prevention lifestyle interventions designed to change lifestyle behaviour following stroke.

Dr Maggie Lawrence, Dr Susan Kerr, Ms Caroline McVey, Dr Jon Godwin

The Scottish Centre for Evidence Based Care of Older People, Glasgow, Scotland: a Collaborating Centre of the Joanna Briggs Institute

Executive Summary

Background

Each year, approximately 15 million people worldwide have a stroke; of these, five million die and another five million are chronically disabled. Stroke recurs in approximately 25% of patients during the first five years post-stroke; recurrence may result in death, increased disability or institutionalisation. Modifiable risk factors for recurrent stroke have been identified, and may be addressed by means of behavioural health promotion interventions.

Objectives

This systematic review sought to establish the effectiveness of secondary prevention behavioural interventions, which address one or more modifiable lifestyle risk factors for recurrent stroke i.e. tobacco use, unhealthy diet, physical inactivity and excessive alcohol consumption.

Inclusion criteria

Types of participants

The review included studies that had recruited adults (aged ≥18 years) who had had a stroke, minor stroke or transient ischaemic attack.

Types of intervention

The review considered studies that evaluated behavioural lifestyle interventions, designed to address the prevention of recurrent stroke.

Types of outcomes

Primary outcomes were concerned with lifestyle behaviour change i.e. tobacco use, diet, physical activity and alcohol consumption, and with change in physiological measures e.g. blood pressure, total cholesterol, and Body Mass Index. Secondary outcome measures included psychological outcomes, learning outcomes and incidence of stroke recurrence.

Types of studies

Experimental and non-experimental quantitative studies were considered.

Search strategy

In August 2009, we searched All EMB Reviews, AMED, ASSIA, British Nursing Index and Archive, CINAHL, Conference Proceedings Citation Index - Science, ProQuest dissertation and theses, EMBASE, MEDLINE, PsycINFO, and bibliographies of retrieved papers.

Methodological quality and data extraction

Two review authors independently assessed methodological quality using standardised critical appraisal instruments from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument, and extracted data using a review-specific data extraction form.

Data analysis

Where possible, results from the review papers were pooled in statistical meta-analysis using bespoke software based on the system used by the Early Breast Cancer Trialists Collaborative Group. Where statistical pooling was not possible, findings are presented in narrative form.

Results

Three studies, two RCTs and one quasi-experimental study, involving 581 participants (baseline) were reviewed. Two models of service delivery were reported: shared care and nurse-led. Interventions were delivered to groups or in one-to-one consultations.

Meta-analyses of the pooled lifestyle data favoured the interventions (2p=0.02; here and throughout, 2p represents the two-tailed probability). In terms of physiological outcomes, the pooled data favoured the interventions (2p=0.05), particularly those aiming to reduce blood pressure and cholesterol levels. The pooled secondary outcomes, including perceived health status and stroke knowledge favoured the interventions (2p<0.00001), however, the test for heterogeneity was also highly significant.

Conclusions

Stroke secondary prevention lifestyle interventions are effective in terms of effecting positive change in relation to lifestyle behaviours, physiological and secondary

outcomes. However, there was insufficient evidence to determine the effect of intervention on incidence of stroke recurrence.

Implications for practice

Clinicians should implement stroke secondary prevention interventions which address lifestyle behaviours, physiological factors, psychological outcomes and stroke knowledge.

Implications for research

Further large-scale, well-designed trials are needed to determine the factors that impact on the effectiveness of secondary prevention interventions.

Key words

Stroke; recurrent stroke; lifestyle risk factors; smoking cessation, alcohol consumption, physical activity; diet

Background

Stroke is a common long-term condition. Each year, approximately 15 million people worldwide have a stroke; of these, five million die and another five million are chronically disabled, resulting in considerable burden for individuals, families, wider communities, health and social care services and government exchequers.[1,2]. In 2002, ischaemic heart disease and stroke together accounted for 36% of mortality in the developed world, with stroke being the second highest cause of death and fourth leading cause of disability among adults.[3,4] In the United Kingdom, the incidence is high and stroke is the most common cause of disability in the community-dwelling adult population[1]; the incidence is particularly high in Scotland, with approximately 13,000 new cases per year.[5] Stroke may result in changes to physical, cognitive and affective functioning, and may result in reduced social participation and caregiver strain.[6]

Risk factors for stroke and transient ischaemic attack (TIA) have been identified. A recent large-scale international multicentre, case-control study demonstrated that ten known and emerging risk factors are associated with 90% risk of stroke i.e. hypertension, smoking, waist-to-hip ratio, poor diet, physical inactivity, diabetes mellitus, alcohol intake, psychosocial stress, depression, and cardiac disease.[7] Crucially, many of these factors are amenable to change by means of pharmacotherapy and/or the delivery of lifestyle interventions,[8] and it has been estimated that successful management of vascular risk factors may reduce the incidence of first stroke by 70-80%.[9] Therefore, targeted interventions have the potential to substantially reduce the burden of stroke.

A feature of stroke is that it recurs; it recurs in approximately 25% of patients during the first five years post-stroke. Recurrence may result in death, increased disability or institutionalisation, often resulting in a stepwise decline into dependency.[8,10] In addition, stroke survivors are at particular risk of death (15% at three months post-stroke) from myocardial infarction and from other vascular causes.[11] Risk factors for recurrence are the same as those for first-ever stroke, as described above.[12,13] Recent improvements in the management of stroke have resulted in a decline in the incidence of stroke in many developed countries. Improvements have included the

establishment of organised, direct access, stroke rehabilitation units; the introduction of new treatments such as alteplase for intravenous thrombolysis; improved control of high blood pressure, and increased prescription of statins, combined with a reduction in the general population in the use of tobacco.[6] However, despite these advances, the incidence of stroke remains high and prevalence is rising due to the ageing demographic of the global population.[1,14] Projections of mortality and burden of disease indicate that in 2030 stroke is likely to remain the second highest cause of death worldwide.[15]

In light of the above, it is important that effective health promotion strategies and interventions are implemented, which include interventions designed to address modifiable lifestyle risk factors for stroke and recurrent stroke i.e. tobacco use, alcohol consumption, diet and physical activity, and other modifiable risk factors such as hypertension.[16] Evidence-based guidelines recommend that secondary prevention interventions should be multimodal, i.e. they should combine two key elements: 1) prescription of appropriate medication and 2) active provision of information and education regarding lifestyle risk factors and medication adherence.[16,17] Interventions should be tailored to the needs/priorities of individuals and their families.[17] It is recommended that the design and delivery of such interventions should be informed by behaviour change theory, and in addition to knowledge of appropriate psychological theory, health professionals delivering such interventions should have good knowledge and understanding of the relevant health condition(s) and associated issues.[18] For example, healthcare professionals implementing stroke primary and/or secondary prevention interventions require knowledge and understanding of behaviour change theory, stroke and its effects and the lifestyle risk factors for stroke/recurrent stroke. It is further recommended that interventions should be initiated whilst the patient is still in hospital and that any interventions initiated in hospital should be followed up in primary care.[19,20] However despite the wide availability of published guidelines, it is known that physician adherence to treatment recommendations is suboptimal, both in hospital and following discharge.[8,21] In terms of pharmacotherapy, rates of prescription and treatment with combination therapy (i.e. antiplatelet, antihypertensive and statin) are low,[22] and this is compounded by high rates of non-compliance with prescribed

medication regimes (accidental and non-accidental) amongst patients.[21] A recent Cochrane review recommended that research concerning innovative strategies to assist patients to follow medication prescriptions for long-term conditions should be afforded high priority.[23] Such strategies include educating patients about their health condition, their prescribed medication, and the importance of adhering to their medication regime. However, surveys of stroke populations have demonstrated that stroke patients have poor levels of knowledge regarding stroke risk factors, the need to take immediate action if stroke is suspected, and the purpose of medications prescribed following stroke (e.g.[24,25]). A recent UK-wide survey found that 54% of stroke survivors wanted more information about how to avoid having another stroke,[26] thus highlighting the need for improved stroke information and educational interventions.

To date, research efforts have focused on primary prevention initiatives i.e. pharmacological and lifestyle interventions, and health promotion campaigns that have targeted the general population or high-risk groups.[27] However, despite the fact that international and national evidence–based guidelines support the need for early instigation of secondary prevention measures, including pharmacotherapy and lifestyle interventions,[17,28] scoping searches revealed a dearth of research regarding the effectiveness of multimodal interventions designed to address recurrent stroke. A search was performed in the Cochrane Library of Systematic Reviews, the JBI Library of Systematic Reviews, MEDLINE, CINAHL, DARE, and PsycINFO, and no systematic review was identified, completed or in progress, which aimed to assess the effectiveness of lifestyle interventions following stroke.

Review Questions/Objectives

This systematic review aimed to establish whether lifestyle interventions designed to help prevent recurrent stroke are effective in terms of effecting positive changes to lifestyle risk factor behaviour.

The objectives were to:

1. identify secondary prevention behavioural interventions which addressed one or more modifiable lifestyle risk factors for recurrent stroke i.e. tobacco, physical activity, alcohol, diet
2. determine the effectiveness of identified interventions in improving behavioural, physiological, psychological and/or learning outcomes.

Criteria for considering studies for this review

Types of participants

The review considered studies that included adults (aged ≥18 years) who had had a stroke and/or minor stroke/transient ischaemic attack (TIA) and studies of mixed populations where the stroke data could be extracted. A broad definition of stroke was adopted which included ischaemic stroke, haemorrhagic stroke, subarachnoid haemorrhage and TIA. The review considered studies that included adults with vascular and other co-morbidities. However, studies that included participants with impaired cognition were excluded as this patient group have distinct needs in terms of behavioural interventions.

Types of interventions

The review considered studies that evaluated educational/health promotion interventions and other behavioural interventions designed to address prevention of recurrent stroke.

Types of outcome measures

The review considered studies that included the following primary and secondary outcome measures.

Primary outcome measures

Lifestyle: behaviour change in terms of tobacco use, physical activity, alcohol consumption and/or diet.

Physiological outcomes: blood pressure, cotinine levels, carbon monoxide (CO) levels, blood sugar, blood lipids, weight, Body Mass Index (BMI), waist circumference, mean corpuscular volume (MCV), gamma-glutamyl transferase (GGT).

Secondary outcome measures

Psychological outcomes: wellbeing; life satisfaction; quality of life; self-rated health.

Learning outcomes: knowledge of signs and symptoms of and appropriate response to onset of stroke, knowledge of stroke risk factors, health-related attitudes; beliefs.

Stroke recurrence: the incidence of recurrent stroke and other vascular events amongst the study population.

Types of studies

The review aimed to identify any randomised controlled trials (RCTs) of secondary prevention interventions. Other research designs, such as non-randomised controlled trials, before and after studies, case control studies and cohort studies were also considered for inclusion. These types of studies represent levels E1-3 on the JBI levels of evidence scale, FAME (Appendix I).

Search strategy

The search strategy aimed to find both published and unpublished studies. A three-step search strategy was used. First, a scoping search of MEDLINE and CINAHL was undertaken, followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. Second, a full search was developed, using all identified keywords and index terms (Appendix II), and was run separately in all the databases specified in the review protocol. Third, reference lists were searched for additional studies.

Databases searched

In August 2009, we searched All EMB Reviews, AMED (1985 onwards), ASSIA (1987 onwards), British Nursing Index and Archive 1985–2009, CINAHL, Conference

Proceedings Citation Index - Science, EMBASE (1980 to August 2009), Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1950 to August 2009, ProQuest Dissertation & Theses, PsycINFO 1967–2009.

Initial keywords

Stroke/Cerebrovascular accident, Transient ischaemic attack/ Minor stroke, Health promotion/ Secondary prevention, Alcohol/ethanol, Tobacco, Smoking/cessation, Diet, Healthy eating, Exercise, Physical activity.

Delimiters

Dates (currency): no date limit was set.

Language: no language limit was set, as members of the Collaborating Centre are able to translate papers written in a range of languages.

Bibliographic management

RefWorks was used to store and manage the results of the electronic database searches.

Methods of the review

All identified material was screened for relevance using broad inclusion criteria i.e. 'stroke' and one or more of the four lifestyle behaviours that form the focus of our review i.e. tobacco use, alcohol consumption, diet and physical activity. Where there was insufficient evidence in the title and abstract to make a decision, full-text papers were retrieved. All relevant papers were then screened according to four narrow inclusion criteria relating to study design, population, intervention and outcomes, as described above.

Assessment of methodological quality

Papers selected for retrieval were assessed by two independent reviewers for methodological validity prior to inclusion in the review, using standardised critical appraisal instruments from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix III). We awarded one point for each of the nine or ten items in the individual appraisal instruments. Papers scoring five or more were included in the review. Any disagreements that arose between the reviewers were resolved through discussion.

Data extraction

As described in the review protocol, quantitative data were extracted from papers included in the review using a review-specific data extraction tool developed by authors of the review (Appendix IV). Data extracted included details of interventions (delivery and content), populations, study methods, and primary and secondary outcomes.

Data synthesis

Where possible, odds ratios and their 95% confidence intervals were calculated from the quantitative results and pooled in statistical meta-analysis with 95% confidence intervals. We had originally intended to use JBI software to conduct the meta-analyses. However, the review team was extended to include the statistician (JG) from the Early Breast Cancer Trialists' Collaborative Group (EBCTCG), who used similar methods to those of the EBCTCG to conduct the meta-analyses for this review [29] Odds ratios and 95% confidence intervals are calculated for the intervention effects and logrank variances are shown as an indicator of the 'information content' of each result, being related to the number of events or the effect size as appropriate for each measurement. Heterogeneity was assessed using the standard Chi-square. Where statistical meta-analyses were not possible, findings are presented in narrative form.

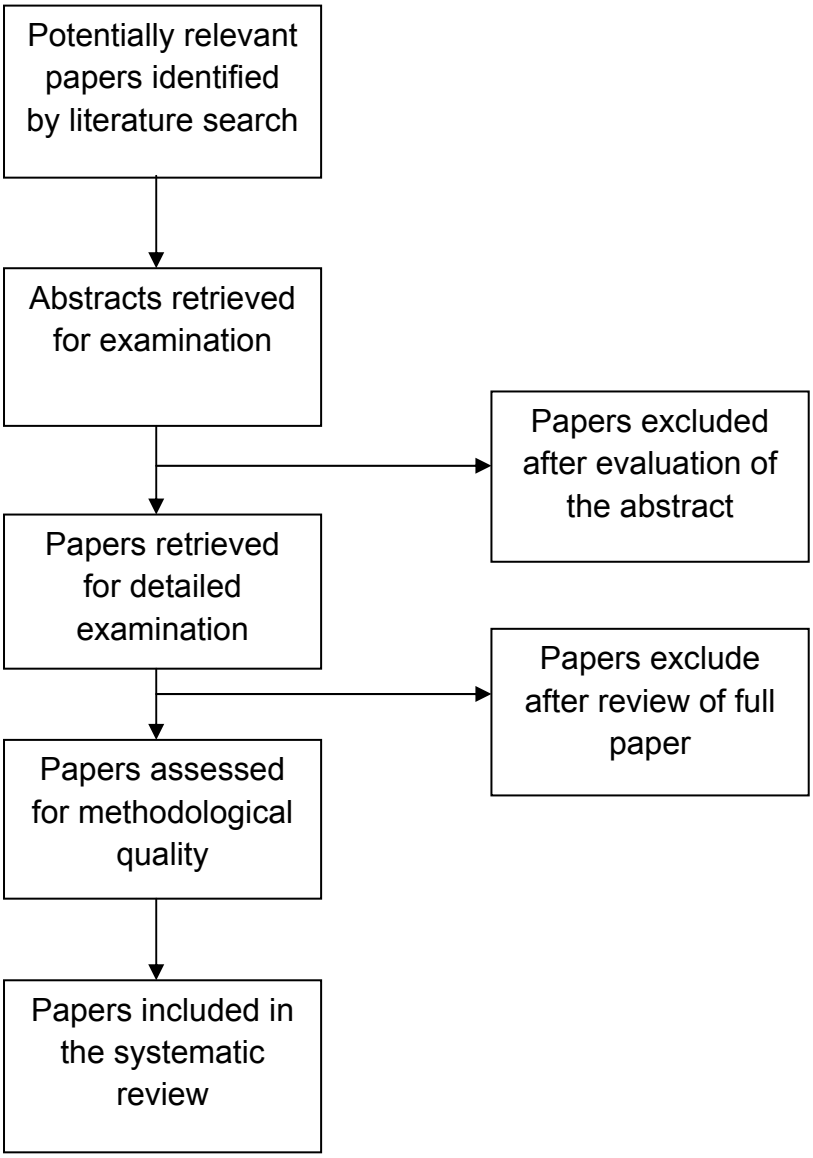
Review Results

Description of studies

Numbers of records/papers at each stage

The Stage 1 database searches retrieved 2,799 bibliographic records, of which 531 were duplicates; therefore, 2,268 were eligible for Stage 2 of the process (Figure 1). In Stage 2, broad inclusion/exclusion criteria were applied i.e. eligible papers were required to have a focus on stroke and secondary prevention. Titles and abstracts of all 2,268 records were read; 2,212 records were excluded and 56 records were considered eligible for submission to Stage 3. In Stage 3, following application of narrow inclusion/exclusion criteria regarding study design, population, intervention and outcomes (see above: Criteria for considering studies for this review), 34 papers were excluded; 22 papers were eligible for submission to Stage 4. In Stage 4, 22 papers underwent a process of critical appraisal following which 19 papers were excluded; three papers remained in Stage 4 (i.e. Sit et al,[30] McManus et al,[31] Joubert et al[32]). At this stage, the reviewers noted that the paper by McManus et al[31] reported follow-up trial data (42-month mean), but provided no baseline data. In a research letter to a journal, which had not been retrieved by the Stage 1 searches, Ellis et al[33] reported baseline and five-month follow up data. A decision was made to include both documents in Stage 4 of the review but to treat them as a single paper for purposes of quality appraisal, data extraction, data analysis and reporting. Details of the data extracted from the four documents included in the review are provided in Appendix V.

Figure 1. Flowchart of study selection



Reasons for the exclusion of papers at the various stages of the review/Assessment of methodological quality

In Stage 2, a large number of studies were excluded (n=2,212), most commonly because they focused on health disorders other than stroke e.g. cardiac disorders and renal disease, or on primary prevention of stroke.

In Stage 3, thirty-four studies were excluded. Thirty-two were excluded because they presented guidelines and recommendations rather than intervention results or because they reported rehabilitation interventions, which focused on motor recovery rather than secondary prevention of stroke. A further two were excluded from the review because the British Library were unable to locate copies of the full text i.e. Chanruengvanich et al[34]; Furtado et al[35] (Appendix VI).

In Stage 4, 22 papers, comprising RCTs/pseudo RCTs (n=7), cohort/case control studies (n=7) and descriptive/case series (n=8), were assessed for methodological quality using the JBI-MAStARI critical appraisal instruments (Appendix III). As a result of this appraisal process, 13 papers were excluded because they failed to meet review-specific quality criteria i.e. they failed to meet five or more of the JBI-MAStARI design-specific methodological criteria. A further three papers were excluded (Pang et al,[36] Lennon et al,[37] Rimmer et al[38]) because, although they appeared to met review inclusion criteria, the three reviewers (ML, CMcV, SK) agreed that the interventions were not designed to address behavioural change. Rather, they were designed to improve cardiac fitness levels[37,38] or prevent secondary complications resulting from physical inactivity[36] with no focus on instigating and/or sustaining behaviour change. Therefore, six papers were eligible for data extraction and analysis (Sit et al,[30] Joubert et al,[32] Ellis et al[33]/McManus et al,[31] Nir et al,[39] Kaplan and Weiss,[40] Rahiman et al[41]).

Following data extraction, the reviewers contacted by email the authors of these six papers to request additional information, which would enable comprehensive completion of data extraction forms. Responses were received from five authors. The authors of three papers (Nir et al,[39] Kaplan and Weiss,[40] Rahiman et al[41]) were unable to provide the detailed review-specific data requested and therefore were excluded from the review, as it was not possible to conduct sufficiently detailed data

extraction. Two of the authors of the three remaining Stage 4 papers were able to supply additional review-specific data, sufficient to enable comprehensive data extraction (i.e. Sit et al[30]; McManus et al[31]). No response was received from Joubert; however, the paper[32] contained sufficient data to support its inclusion in the review. The methodological quality of the three included studies was acceptable according to review criteria i.e. they scored six or more using JBI critical appraisal instruments, although some limitations were noted, as described below (Methodological limitations of included studies).

Papers in languages other than English

The searches retrieved records of several papers written in languages other than English e.g. French, Korean, Polish and Russian. All of these papers were accompanied by English translations of the title and abstract, which provided sufficient information to enable screening in Stage 2, and where appropriate, Stage 3 of the review process. No papers in languages other than English met all of the review inclusion criteria; consequently, only English language papers were included in Stage 4.

Attributes of included studies

As discussed, three studies (reported in four papers) were included in Stage 4. Two papers, Ellis et al[33]/McManus et al[31] reported the same RCT; one at baseline and three-month follow–up,[33] the other at 42-month follow-up.[31] The papers by Joubert et al[32] and Ellis et al[33]/McManus et al[31] reported the results of RCTs, Sit et al[30] reported the results of a quasi-experimental study i.e. they used group randomisation. An overview of the key characteristics of the three studies, including study design, aim, setting, population, intervention design and delivery, and primary and secondary outcomes, is presented in Appendix V.

Participant characteristics

Review data were extracted from four papers reporting three studies, which included three completed trials with 581 participants at baseline (table 1). The mean age and gender of participants is presented in table 1; further details are provided in Appendix V). Joubert et al[32] recruited participants whilst they were in-patients, following a TIA or complete stroke. Sit et al[30] recruited participants who were living in the community and who had had a 'minor stroke'. Ellis et al[33] recruited participants who had had a TIA, stroke, or amaurosis fugax (loss of vision in one eye due to a temporary lack of blood flow to the retina, which may be a sign of impending stroke) within the previous three months.

Table 1: Participants by number age and gender

Study	Intervention			Control		
	Number	Mean age (SD)	%male	Number	Mean age (SD)	%male
Sit et al[30]	107	62.83 (10.25)	55	83	64.02 (12.03)	50
Joubert et al[32]	91	63.4 (13.7)	58	95	68.2 (12.7)	52
	Number	Mean (CI)	%male	Number	Mean (CI)	%male
Ellis et al[33]/ McManus et al[31]	100/49	64.3 (62.4 - 66.1)/not reported	54/not reported	105/53	65.8 (64.0-67.5)/not reported	52/not reported

Characteristics of the interventions

The studies were conducted in three different countries i.e. China (Hong Kong),[30] Australia[32] and Scotland,[33/31] all of which have different systems of healthcare delivery. Two models of delivery were reported. Joubert et al[32] described a shared-care model, in which care was shared between hospital, where the intervention was initiated, and community (general practitioner); Sit et al[30] and Ellis et al[33]/McManus et al[31] reported nurse-led models, which were delivered in the community[30] and in hospital-based outpatient clinic[33/31] and. All three interventions were of short duration, however, the length and intensity of follow-up from healthcare professionals varied. Sit et al[30] delivered their intervention in 2-hourly sessions conducted over the course of eight weeks (2 hours per week); follow-up data were collected three months later. Joubert et al[32] delivered their educational intervention during the participants' in-patient hospital stay. Telephone tracking was used to collect data prior to follow-up appointments with the participants' GPs at two weeks, and three,

six, nine and 12 months post-intervention. Family doctors were provided with contemporary evidence-based guidelines, therapeutic goals and recommendations to promote 'best practice management' (p.280).[32] Ellis et al[33]/McManus et al[31] delivered their educational intervention monthly over three months, during 30-minute outpatient department appointments; follow-up data were collected at five months and at 42 months (mean).

Sit et al's[30] educational intervention adopted a self-care approach and was designed to equip participants with self-monitoring skills, including self-monitoring and recording of blood pressure, and medication concordance. Ellis et al[33]/McManus et al[31] evaluated a health education (including medication compliance) and counselling intervention. Joubert et al[32] reported a multimodal intervention (Integrated Care for the Reduction of Secondary Stroke (ICARUSS)) which combined prescription of appropriate secondary prevention medication e.g. antihypertensive medication and statins, with an educational component delivered by a hospital-based stroke nurse coordinator, and frequent therapeutic follow-up provided by family doctors (five times in 12 months).

Educational component

All three interventions incorporated an educational component, which differed across the studies in relation to approach, scope and focus.

Sit et al[30] aimed to empower participants by providing them with the knowledge and skills they required in order to self-manage their stroke-related health care. They used interactive methods to teach self-care skills, which included self-health monitoring skills, stroke knowledge, medication knowledge and goal setting techniques. The educational component included specific sessions on diet and physical activity however, education and skills training focused on lifestyle-based goals determined by individual participants. In terms of diet, Sit et al's[30] intervention was designed to take into account culturally relevant aspects of dietary behaviour, including social interaction. Their intervention addressed diet from a self-management perspective that enabled participants to make informed dietary

choices, in accordance with individual preferences and affordability. Together with their 'family partner', participants were encouraged to review their diet, identify any associated problems, set appropriate goals, and plan and implement changes. Sit et al[30] considered their culturally relevant approach to be an essential aspect of the intervention.

The educational component of Joubert et al's[32] intervention focused on the importance of effective management of modifiable risk factors for ischaemic stroke and parenchymal haemorrhage. It included early commencement of education by the nurse coordinator regarding behaviour modification i.e. smoking cessation, reduction in alcohol intake, maintenance of recommended BMI and deliberate physical exercise. The nurse also educated patients and carers regarding stroke risk factors and the warning signs for stroke for regarding warning signs for stroke. No further detail is provided.

Ellis et al[33]/McManus et al[31] used one-to-one educational and counselling techniques. Participants were given individual advice on lifestyle changes, and the importance of medication compliance and its relevance to secondary prevention. Lifestyle issues were discussed, taking into account the circumstances and functional abilities of individual patients. Verbal information was reinforced by written information, which was selected for its relevance to the individual. Patient-held records, which detailed individual's risk factors and recommended risk factor targets, were updated at each session (maximum: three sessions).

Methodological quality

Methodological quality of RCTs

Randomisation

Joubert et al[32] highlight a limitation in the random allocation to groups in their study. Fourteen GPs had two patients in the trial. For 12 of these, the second participant was allocated to the same group as the initial participant in order to avoid contamination. The majority of the 12 participants were allocated to the intervention group and this led to a slight imbalance in treatment allocation. The remaining two

were missed, which resulted in two GPs being responsible for two patients, who were in different groups.

Similarity of treatment and control groups

Joubert et al[32] noted that participants in the intervention group were younger than those in the control group (table 1, below), and suggest that this may have influenced differences in some of the 12-month outcomes reported for the two groups. For example in the control group, modified Rankin scores were lower, indicating higher levels of physical function, and levels reported physical activity and medication compliance (Warfarin) were higher.

Sample size

At 42-month follow-up, the small number of participants (n=102) in McManus et al's[31] study meant that the study was 'relatively' underpowered (p.103)[31], as noted by the authors. As a result, only major differences between the intervention group and the control group would have been detected, and therefore a type II error may exist in some instances where differences were not shown to be significant.

In McManus et al's[31] study, 51 participants (51%) from the intervention group and 52 participants (50%) from the control group dropped out. In Joubert et al's[32] study, 32 participants (26%) from the intervention group and 15 participants (14%) from the control group dropped out. These attrition rates, and particularly that evident in the Ellis et al[33]/McManus et al[31] study, may represent a systematic bias. In such circumstances, intention to treat analysis should be used to reduce any bias due to changes in the characteristics between control and treatment groups. All three studies were potentially subject to attrition bias. However, this approach was only adopted by Sit et al[30] and by Ellis et al[33] but not by McManus et al[31] or Joubert et al.[32]

Methodological quality of the quasi-experimental study

Validity and reliability of outcome measures

Smoking status was determined by self-report and was not biochemically validated in any of the studies. The Russell Standards[42] recommend that RCTs that aim to determine whether smoking cessation interventions have been effective use biochemical verification (e.g. monitoring of expired CO). Further, participant self-report, which is known to be prone to misreporting,[43] was used by Sit et al[30] and McManus et al[31] to measure specific outcomes including number of cigarettes smoked, dietary intake, medical history and vascular recurrence.

Attrition and intention to treat analysis

In Sit et al's[30] study, 28 participants (25%) from the intervention group and 16 participants (19%) from the control group dropped out.

Generalisability

In terms of generalisability, it should be noted that participants in the study by Sit et al[30] appear to have had healthy lifestyles prior to stroke, and consequently prior to the intervention, compared with the general population in the UK, for example. In Sit et al's[30] study, at baseline only 11 (5.6%) participants smoked, 12 (6.5%) drank alcohol and 150 (78.9%) reported walking for exercise. In the UK, 22% of the population are smokers;[44] 21% of men and 10% of women regularly consume more than twice the recommended limits for low-risk drinking,[45] and in Scotland only 42% of the population meet physical activity recommendations.[46]

Also of note is that Sit et al's[30] intervention was delivered to a group of participants with a relatively high level of educational achievement (i.e. 60% secondary school and above), and therefore may not be transferable to people with lower levels of education.

Outcomes

Our scoping searches resulted in the identification of a comprehensive range of physiological outcomes, including those reported below. However, none of the

studies reported the following physiological outcomes: cotinine levels, carbon monoxide monitoring, waist circumference, mean corpuscular volume, and gamma-glutamyl transferase. Similarly a range of secondary outcome measures were identified, including those reported below. However, none of the studies included in the review reported outcomes associated with wellbeing and life satisfaction, or health-related attitudes and beliefs.

Results

Data are combined in meta-analysis and where not, are presented in narrative summary, as appropriate.

Primary outcomes

Primary outcomes were concerned with lifestyle behaviour change and physiological outcomes.

Lifestyle behaviour change

Outcomes relating to lifestyle behaviour change included smoking status, physical activity (measured in terms of walks taken for exercise), alcohol consumption and dietary factors.

Smoking status

All three studies provided information on smoking status. It appears that results are reported on a point prevalence basis, rather than continuous abstinence, although none of the papers makes this clear. As noted above, there was no bio-chemical verification of smoking status in any of the studies.

Sit et al[30] state that 6/107 (5.6%) of the intervention group and 5/83 (6%) of the control group were current smokers at baseline. They report no significant change in smoking status at one week or three months post intervention, but provide no relevant data.

Joubert et al[32] and Ellis et al[33]/McManus et al[31] also reported no significant difference in smoking status between intervention and control groups, post intervention (table 2).

The prevalence of smoking in Joubert et al's[32] study remained similar in each group over time. Prevalence of smoking in both the intervention and control groups in the study undertaken by Ellis et al[33]/McManus et al[31] reduced between baseline and 42 months. The authors do not speculate on the reasons for this. However, as noted above, the sample reduced by approximately 50% between baseline and collection of follow-up data at 42 months. Eleven of the intervention group and 14 of the control group had died during this time. A further 19 of the intervention group and 11 of the control group declined to participate in the follow-up study. No information is presented on the smoking status of those who died or refused to participate. Therefore, it cannot be assumed that the reduction in prevalence of smoking in both groups was as a result/wholly as a result of participants actually stopping smoking.

Table 2: Smoking Status

Study	**Time point**	**Intervention** n (%)	**Control** n (%)	χ^2 **(df)**	**p-value**
Joubert et al[32]	Baseline	13/89 (15%)	9/90 (10%)		
	12 mths	14/91 (15%)	10/92 (11%)	0.8 (df1)	0.4
Ellis et al[33]/ McManus et al[31]	Baseline	36/100 (36%)	42/105 (40%)		
	42 mths	13/49 (26.5%)	14/53 (26.4%)	0.1 (df1)	0.73

Physical activity (walking for exercise)

Two studies, one RCT and one quasi-experimental study, reported deliberate walking for exercise as an outcome.[30,31] in a RCT, Joubert et al[32] found a statistically significant difference between intervention and control groups in mean number of walks taken per week (table 3). The number of walks increased between baseline and 12 months in the intervention group and decreased over the same period in the control group.

Table 3: Deliberate exercise, walks per week

Study	**Time point**	**Intervention (n=91)** Mean (SD)	**Control (n=95)** Mean (SD)	**t-test**	**ANCOVA**
Joubert et al[32]	Baseline	3.9 (2.9)	4.3 (2.8)		
	12 months	4.7 (2.5)	3.6 (2.7)		
	Change	+0.8 (3.2)	-0.7 (3.2)	p=0.001*	p<0.001

The quasi-experimental study undertaken by Sit et al[30] also reported on 'walking for exercise.' The authors state that an exercise scale was used to assess exercise pattern and that participants were 'asked to indicate the type and frequency of physical activity'; however, results were presented as the percentage of participants who 'walked for exercise,' with no additional data being provided. As indicated in table 4, 'walking for exercise' declined over time in both groups (from baseline to three months). The authors argue that walking for exercise was maintained more successfully in the intervention group than the control group, which showed a progressive decline at one week and three months post-intervention. They state that, using chi-square analysis, the difference between groups at three months was significant ($p<0.001$). However, scrutiny of the results by our statistician (JG) suggests that differences between groups from baseline to one week and from baseline to three months, using chi-square analyses, are not significant. Our chi-square results are presented in table 4.

Note: Here and elsewhere i.e. re Diet (tables 6 and 7), Diastolic BP (table 11), Total cholesterol (table 13), HbA1c (table 15), BMI (table 16) and Stroke knowledge: risk factors (table 17), we have been unable to reconcile our results with those reported by the authors. However, we did not have access to the primary data. Therefore, we have used the summary figures as presented by the authors to perform our analyses; in some instances there are discrepancies between their calculations and ours that we are unable to explain.

Table 4: Participation in walking for exercise

Study	**Time point**	**Intervention** n (%)	**Control** n (%)	χ^2 **(df)**	**p-value**
Sit et al[30]	Baseline	84/107 (78.9%)	60/83 (72.3%)		
	1 week	84/107 (78.9%)	53/83 (63.9%)	0.7 (df1)	2p=0.4
	3 months	60/77 (77.1%)	39/70 (55.4%)	1.9 (df1)	2p=0.2

Note: Throughout the report '2p' denotes a two-tailed probability. Where 'p' is given this is the authors' result, which may also be two-tailed.

Alcohol consumption

Two studies, one quasi-experimental study and one RCT, reported on alcohol consumption. Sit et al[30] state that 7/107 (6.5%) of the intervention group and 4/83 (4.8%) of the control group were 'current drinkers' at baseline. They state that there was no significant change in drinking status at one week or three months post intervention, but provide no additional data.

Joubert et al[32] measured alcohol consumption as drinking more than one standard drink per day (self-report). At 12 months post-intervention, there was no significant difference between groups in terms of number/percentage of people who drank more than one standard drink per day (table 5).

Despite the lack of a significant difference between groups, it is of note that whilst the percentage of people who drank more than one standard drink declined in the intervention group, it rose in the control group. However, as indicated in Figure 2, while the OR is 0.67, the confidence intervals ranged from 0.40 to 1.11, thus crossing the line of no effect.

Table 5: Alcohol consumption (> 1 standard drink per day)

Study	**Time point**	**Intervention** n (%)	**Control** n (%)	χ^2 **(df)**	**p-value**
Joubert et al[32]	Baseline	22/91 (24%)	18/95 (19%)		
	12 months	13/91 (14%)	21/95 (22%)	2.5 (df1)	p=0.1

Diet

Only one study recorded a dietary outcome i.e. Sit et al[30]. Self-report data were collected on dietary intake in the previous two weeks, including type and frequency of food. Data collection focused on consumption of salted preserved food, cooking methods e.g. frying, use of additional sauces, and eating food with a high saturated fat content. The authors report statistically significant differences between groups over time, in relation to consumption of poultry bones (local Chinese cuisine, which has a high saturated fat content) and salt intake.

In relation to consumption of poultry bones, the authors report that the decline in consumption in the intervention group, compared to the control group, was statistically significant over time. However, scrutiny of the results by our statistician (JG) suggests that differences between groups from baseline to one week and from baseline to three months, using chi-square analyses, are not significant and are presented in table 6. The authors' within group comparisons are reported in table 6.

Table 6: Consumption of thick poultry bone soup

Study	Time points	Intervention n (%)	Control n (%)	χ^2 (df)	p-value
Sit et al[30]	Baseline	33/107 (31.2%)	25/83 (30.1%)		
	1 week	26/107 (23.9%)	19/83 (22.9%)		
	3 months	16/77 (21.1%)	18/70 (25.3%)		
	Cochran's Q Test	6.867	2.333		
	p value	**0.032**	0.311	0.4 (df1)	2p=0.5

Salt intake appears to have been assessed on a scale of 1-5, with the lower score indicating less frequent consumption of salted preserved food; no additional detail is provided. Sit et al[30] state that within group comparisons show that salt intake declined significantly in the intervention group, but not the control group (table 7). However, our own calculations looking at between group comparisons and comparisons over time undertaken using a test akin to the t-Test demonstrate that the results are not significant (2p=0.7).

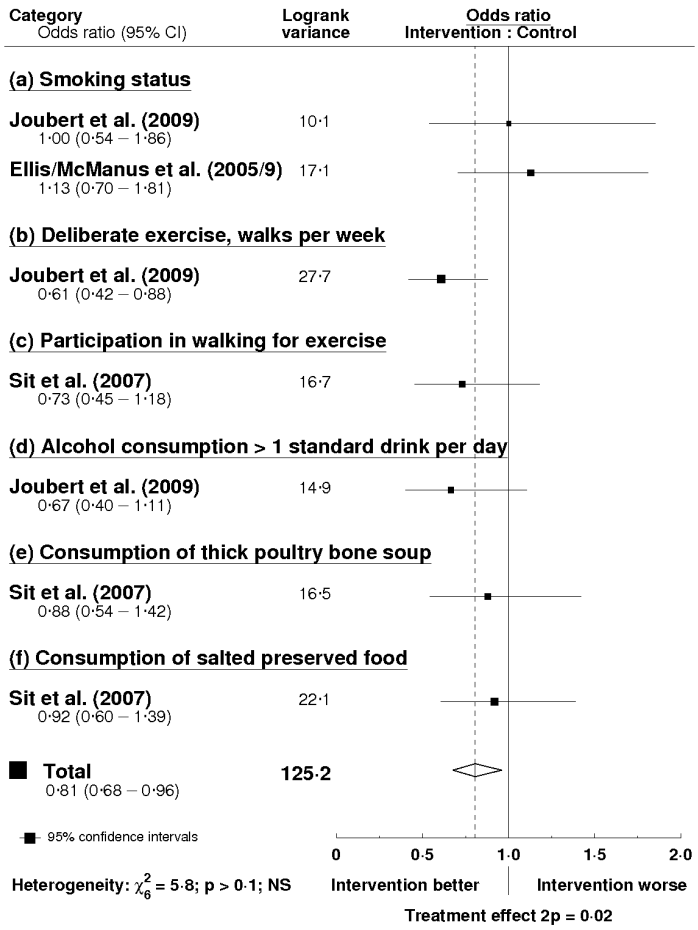
Table 7: Consumption of salted preserved food

Study	Time point	Intervention Mean/SD	Control Mean/SD
Sit et al[30]	Baseline	2.03 (0.87)	2.13 (0.86)
	1 week	1.82 (0.79)	2.01 (0.81)
	3 months	1.83 (0.76)	2.01 (0.87)
	Friedman	11.2	3.94
	p value	0.004	0.14

Meta-analysis

The goal of the meta-analysis of the lifestyle data was to pool in a fixed effects model the findings from a heterogeneous group of interventions to determine whether any intervention was better than none. The pooled data are presented in Figure 2 (below). Odds ratios and confidence intervals are presented for each variable and for the pooled data. As indicated, the pooled results are significant and favour the interventions (treatment effect 2p=0.02). The purpose of the 'forest plot' is largely illustrative as a graphical interpretation of the data. We have estimated the effect sizes, which are similar, because the degree of heterogeneity is not significant, and none of the interventions are mutually exclusive. In terms of clinical heterogeneity, the meta-analysis demonstrates that intervention is better than no intervention and that the beneficial effect is likely to be additive e.g. stopping smoking and reducing alcohol consumption is likely to increase the beneficial effect of the intervention.

Figure 2: Forest plot: Lifestyle Behaviour



Physiological outcomes

Reported physiological outcomes included blood pressure, total cholesterol, random blood glucose, HbA1c (average plasma concentration levels of glucose over a period of two to three months), and Body Mass Index (BMI).

Systolic blood pressure

Two studies reported systolic and diastolic blood pressure as outcome measures.

The RCT undertaken by Joubert et al[32] set a 12-month target for systolic blood pressure of <140 mmHg. The authors report that this target was reached by 66/88 (75%) of the intervention group compared to 52/90 (58%) of the control group. This difference between groups was statistically significant (χ^2 = 5.9 (df1), p=0.015). Mean blood pressure levels[32] are presented in table 8. Again, the difference between groups was statistically significant, with the mean score reducing in the

intervention group and increasing in the control group between baseline and 12 months post-intervention.

Table 8: Systolic blood pressure (Joubert et al[32])

Study	Time point	Intervention mmHg mean (SD)	Control mmHg mean (SD)	t-test	ANCOVA
Joubert et al[32]	Baseline	134.2 (17.0)	131.2 (19.2)		
	12 months	128.5 (13.7)	134.5 (19.4)	p=0.02	p=0.04

In the RCT undertaken by Ellis et al[33]/McManus et al[31] systolic blood pressure was considered to be controlled if it fell below the target set in contemporary UK guidelines i.e. <145 mmHg. Systolic blood pressure in both the intervention and control groups was below this level at 42 months (table 9). However, the difference between the groups was not significant when compared using an independent sample t-test.

Table 9: Systolic blood pressure (Ellis et al[33]/McManus et al[31])

Study	Time point	Intervention	Control	p-value
		mmHg mean (CI)	mmHg mean (CI)	
Ellis et al[33]/ McManus et al[31]	Baseline	156.2 (150.7-161.7)	151.1 (145.6 - 156.6)	
		mmHg mean (SD)	mmHg mean (SD)	
	42 months	143 (18.8)	139 (21.6)	0.38

Diastolic blood pressure

Joubert et al[32] did not report a target for diastolic blood pressure. Mean diastolic blood pressure had risen slightly in both groups at 12 months, compared to baseline (table 10). Between-group differences were assessed using an independent sample t-test and were found not to be significant.

Table 10: Diastolic blood pressure (Joubert et al[32])

Study	Time point	Intervention mmHg mean (SD)	Control mmHg mean (SD)	p-value
Joubert et al[32]	Baseline	76.1 (11.7)	75.6 (12.0)	
	12 months	77.3 (8.3)	79.1 (8.9)	0.37

In the RCT undertaken by Ellis et al[33]/McManus et al[31] diastolic blood pressure was considered to be controlled if it fell below the target described in contemporary UK guidelines i.e. < 85 mmHg. At follow-up, mean diastolic blood pressure in both groups was below the target level (table 11). Between-group differences were assessed using an independent sample t-test and found by the authors not to be significant (p=0.74) (table 11).

Table 11: Diastolic blood pressure (Ellis et al[33]/McManus et al[31])

Study	Time point	Intervention	Control	p-value
		mmHg mean (CI)	mmHg mean (CI)	
Ellis et al[33]/ McManus et al[31]	Baseline	83.4 (79.7-87.1)	80.0 (76.8-83.2)	
		mmHg mean (SD)	mmHg mean (SD)	
	42 months	74.0 (10.3)	74.0 (12.2)	p=0.74

Total cholesterol

Cholesterol was measured as an outcome in two studies.[32,31/33] Cholesterol was considered to be controlled if it fell below guideline recommendations i.e. <5.18mmol/L (Joubert et al[32]) and <5 mmol/L (Ellis et al[33]/McManus et al[31]).

In Joubert et al's[32] RCT, mean total cholesterol levels had dropped in both groups to below the desired level at 12 months post-intervention (table 12). Between group differences were assessed using an independent sample t-test and found not to be significant.

Table 12: Total cholesterol (Joubert et al[32])

Study	Time point	Intervention mmol/l mean (SD)	Control mmol/l mean(SD)	p-value
Joubert et al[32]	Baseline	5.1 (1.0)	5.2 (1.4)	
	12 months	4.9 (1.0)	5.0 (1.0)	p=0.74

In the RCT undertaken by Ellis et al[33]/McManus et al[31] although mean scores dropped in both groups to levels below the target mmol/l (table 13), the authors report that differences between groups, when compared using an independent sample t-test were not significant (p=0.23).

Table 13: Total cholesterol (Ellis et al[33]/McManus et al[31])

Study	Time point	Intervention	Control	p-value
		mmol/l mean (CI)	mmol/l mean (CI)	
Ellis et al[33]/ McManus et al[31]	Baseline	5.8 (5.49-6.11)	5.7 (5.46-5.94)	
		mmol/l mean (SD)	mmol/l mean (SD)	
	42 months	4.3 (1.2)	4.5 (0.9)	p=0.23

Diabetic control

Only Ellis et al[33]/McManus et al[31] recorded random blood glucose and HbA1c as outcome measures.[33/31] Blood glucose was considered to be controlled if it fell below the target level described in contemporary guidelines i.e. random blood glucose <8.0 mmol/L and HbA1c <7.5%.

Random blood glucose

At baseline, the mean random glucose level in the intervention group was higher than the control group (table 14). Levels in the control group fell to below target level at 42 months, but remained slightly above target level in the intervention group. However, there was no significant difference between groups when compared using an independent sample t-test.

Table 14: Random blood glucose

Study	Time point	Intervention	Control	p-value
		Mean mmol/l (CI)	Mean mmol/l (CI)	
Ellis et al[33]/ McManus et al[31]	Baseline	10.73 (8.63 -12.83)	9.94 (8.26-11.62)	
		Mean mmol/l (SD)	Mean mmol/l (SD)	
	42 months	8.1 (5.7)	7.1 (3.5)	2p=0.31

HbA1c

At baseline, the mean HbA1c level in the control group was higher than the intervention group (table 15). Levels in the control group fell over time (between baseline and 42 months) and rose in the intervention group. The authors state that, when compared using an independent sample t-test the differences between the groups were not significant (p=0.43); however our calculations, using the available data, suggest that the difference was somewhat significant and that the difference was in favour of the control (table 15). That said, as indicated by the authors, data were not collected from every participant with diabetes resulting in attrition due to an unintended observer bias. In addition, the drop-out rate between Time 2 and Time 3 was high in this study and this result could have been influenced by a systematic bias in drop-out across the groups.

Table 15: HbA1c

Study	Time point	Intervention	Control	p-value
		Mean (CI)	Mean (CI)	
Ellis et al[33]/ McManus et al[31]	Baseline	7.54 (6.47-8.61)	7.89 (7.26-8.52)	
		Mean (SD)	Mean (SD)	
	42 months	8.0 (1.9)	7.5 (1.5)	2p=0.02

BMI

Only Joubert et al[32] recorded BMI as an outcome. At baseline, mean BMI in both groups was identical; at 12 months post-intervention, mean BMI had reduced in the intervention group and increased in the control group (table 16). The authors report

that the differences between groups and over time were significant (t-test p=0.04; ANCOVA p=0.007). However, our results are not significant (table 16).

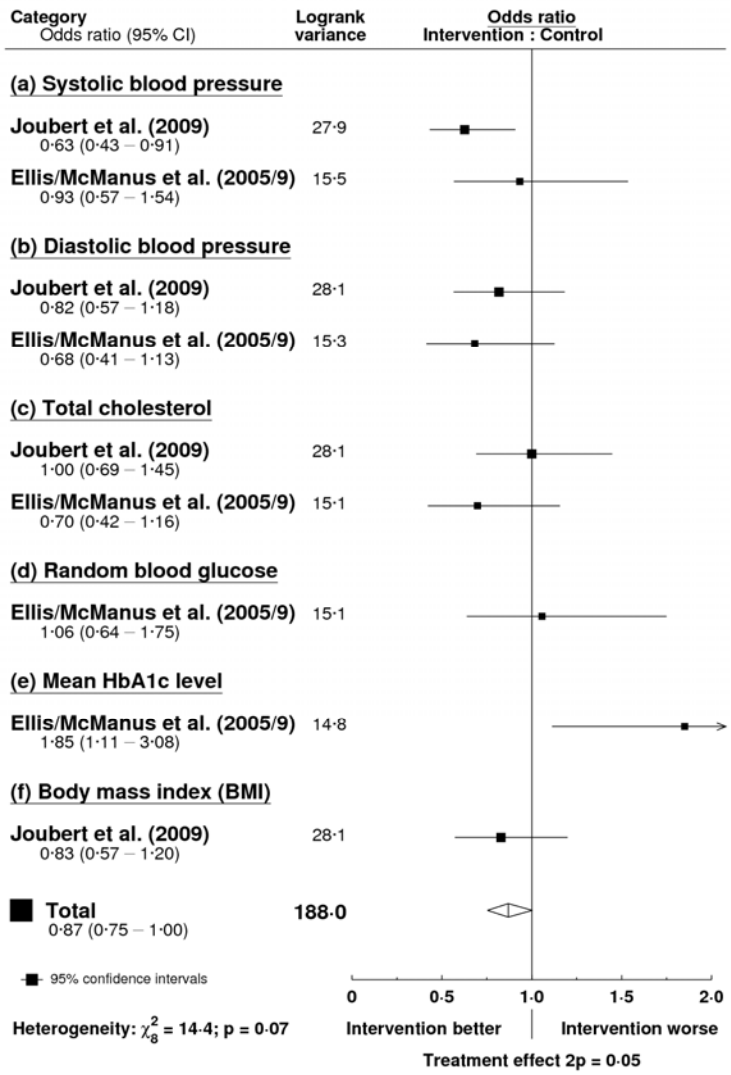
Table 16: BMI

Study	**Time point**	**Intervention** mean (SD)	**Control** mean (SD)	**t-test**	**ANCOVA**
Joubert et al[32]	Baseline	28.1 (5.8)	28.1 (5.6)		
	12 months	27.5 (5.4)	28.7 (6.3)	p=0.04	p=0.3

Meta-analysis

The pooled physiological data are presented in Figure 3 (below). As before, the goal of the meta-analysis was to determine whether the overall picture is generally in favour of the interventions (or not). As indicated, the pooled results favour the interventions and are at the 5% level of significance. The Chi-square test for heterogeneity was not significant, which suggests similarities in the variables that have been pooled. In terms of clinical heterogeneity, the meta-analysis demonstrates that intervention is better than no intervention and because the beneficial effect is likely to be additive, multiple interventions might be better than a single one.

Figure 3: Forest plot: Physiological outcomes



Secondary outcome measures

Secondary outcome measures were concerned with psychological outcomes, learning outcomes and recurrence of stroke and/or other vascular episodes.

Psychological outcomes

Psychological outcome measures included quality of life scales and self-rated health.

Quality of Life

Joubert et al[32] used a validated instrument, the Assessment of Quality of Life Questionnaire (AQoL),[47] to assess quality of life at baseline and 12 months post-

intervention. AQol has a maximum score of 45; a higher score indicates poorer quality of life. Joubert et al[32] reported a significant difference in AQoL scores between groups and over time (table 17). In the intervention group, AQol scores remained almost constant over time but worsened significantly in the control group.

Table 17: Quality of Life

Study	Time point	Intervention Mean (SD)	Control Mean (SD)	t-test	ANCOVA
Joubert et al[32]	Baseline	26.0 (6.8)	26.7 (6.1)		
	12 months	26.4 (5.3)	29.7 (6.2)	p=0.002	p=0.012

Perceived Health Status

Ellis et al[33]/McManus et al[31] used Euroqol[48] to assess perceived health status at 42 months. While they did appear to assess perceived health status at baseline and 5 months post-intervention, the data are presented in a manner that prevents comparisons between groups and over time. We have, therefore, not reported these data.

Learning outcomes

Learning outcomes were concerned with stroke-related knowledge, which included aspects such as knowledge of stroke warning signs, risk factors, and actions required in case of suspected recurrent stroke.

Knowledge of risk factors

Stroke knowledge was measured in two studies; Joubert et al[32] and Sit et al.[30]

Joubert et al[32] reported on nine knowledge–related outcomes (risk factors), including cholesterol management and alcohol intake, of which seven were found to be significantly positively affected as a result of the intervention. However, participants were asked whether they recalled receiving advice about these secondary prevention issues. The authors did not report measurement of participants' understanding or knowledge of these issues; therefore, we have not reported these data.

In the quasi-experimental study undertaken by Sit et al[30] a 'knowledge of stroke scale', modified from Cheung et al[49], was used to assess participants' knowledge of

risk factors. A summative score was calculated, ranging from 0-100, with the higher score representing a greater number of correct responses. Knowledge of risk factors rose at one week post-intervention and dropped below the baseline level three months after the intervention (table 17). The authors report that the within group differences were not statistically significant. However, our own calculations looking at between group comparisons and comparisons over time (baseline to 3 months), undertaken using a test akin to the t-test, demonstrate that the results are significant (baseline to 1 week 2p=0.5; baseline to 3 months 2p=0.04). As indicated (Table 17), there appeared to be a short-term improvement, more marked for the intervention group. Knowledge scores then deteriorate, but more slowly in the intervention than in the control group.

Table 17: Stroke knowledge: risk factors

Study	**Time point**	**Intervention** mean (SD)	**Control** mean (SD)
Sit et al[30]	Baseline	85.66 (1.45)	77.02 (2.27)
	1 week	87.18 (1.31)	77.75 (2.18)
	3 months	84.86 (1.66)	75.26 (2.22)
	Friedman	2.82	0.63
	p-value	0.244	0.731

Stroke knowledge: warning signs

Knowledge of warning signs rose at 1 week post-intervention but dropped slightly three months after the intervention. The authors report that the within group differences were statistically significant (table 18). Our own calculations looking at between group comparisons and comparisons over time undertaken using a test akin to the t-test confirm that the results are highly significant (2p<0.00001).

Table 18: Stroke knowledge: warning signs

Study	**Time point**	**Intervention** mean (SD)	**Control** mean (SD)
Sit et al[30]	Baseline	70.87 (2.74)	71.69 (3.23)
	1 week	83.95 (2.07)	76.51 (2.92)
	3 months	81.88 (2.34)	74.70 (3.05)
	Friedman	23.38	2.45
	p-value	p<0.001	p=0.293

Stroke knowledge: seek help

Knowledge of help seeking (knowing the appropriate action to take i.e. phoning the emergency service, if a stroke or TIA is suspected) rose at 1 week post-intervention but dropped slightly three months after the intervention. The authors report that the within group differences were statistically significant (table 19). Our own calculations looking at between group comparisons and comparisons over time confirm that the difference between the groups was highly significant (table 19). Chi-square(1) = 24.8, 2p < 0.00001.

Table 19: Stroke knowledge: seek help

Study	**Time point**	**Intervention** number (%)	**Control** number (%)
Sit et al[30]	Baseline	20 (18.3)	14 (16.3)
	1 week	107 (100)	36 (43.8)
	3 months	72 (93.6)	22 (31.9)
	Cochran	106.86	28.53
	p-value	p<0.001	p<0.001

Stroke recurrence

Only Ellis et al[33]/ McManus et al[31] reported on recurrence of vascular events, which included transient ischaemic attacks (TIAs), stroke and events related to ischaemic heart disease (table 20).[33/31] Information was gathered using a self-report measure. Differences between groups were not significant.

Table 20: Recurrence of vascular events

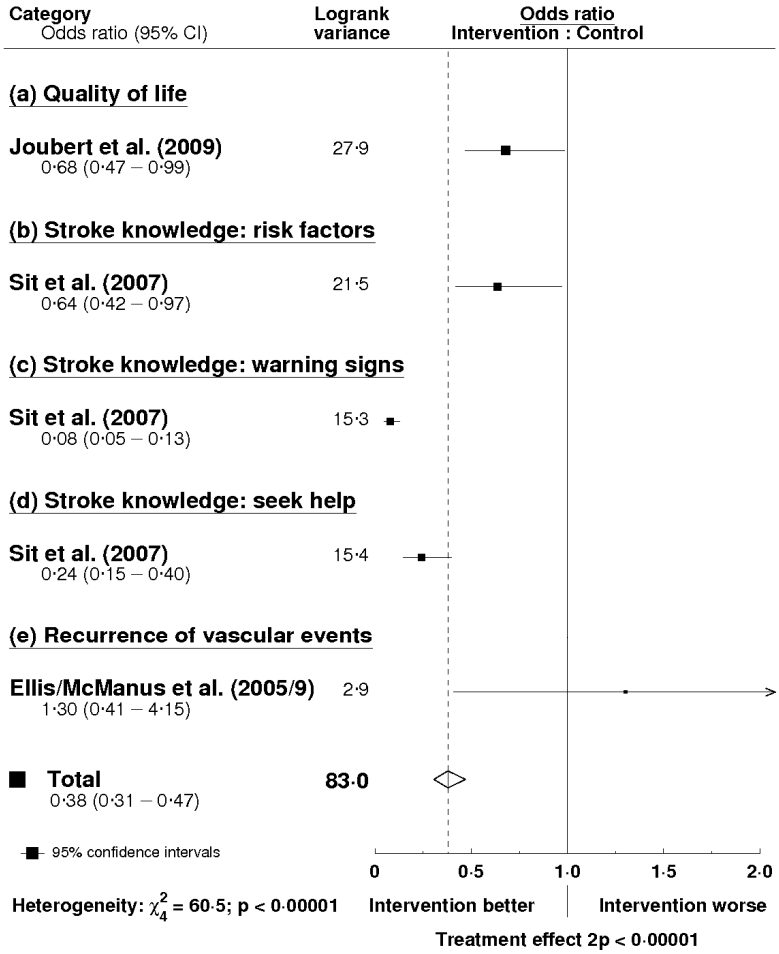
Study	**Time point**	**Intervention** number of events (number of patients)	**Control** number of events (number of patients)	**p-value**
Ellis et al[33]/ McManus et al[31]	42 months	25 (7)	13 (6)	p=0.78

Meta-analysis

The pooled physiological data are presented in Figure 4 (below). The Chi-square test for heterogeneity was highly significant which suggests large differences in the variables that have been pooled. However, as discussed previously, the evidence base is so small and the numbers in the individual trials are so limited that currently

we do not have sufficient statistical power to consider them in sub-groups. As indicated, the pooled results are highly significant and favour the interventions.

Figure 4: Forest plot: Secondary outcome measures



Discussion

Overview of results

Four papers reporting three studies were reviewed; two studies reported RCTs (Joubert et al,[32] Ellis et al[33]/McManus et al[31]) and one reported a quasi-experimental study (Sit et al[30]). The review papers reported three trials with 581 participants at baseline, recruited following a TIA/ complete stroke[32,33/31], or 'minor stroke'.[30] The studies were conducted in three different countries i.e. China (Hong Kong)[30], Australia[32] and Scotland[33/31], with different systems of healthcare delivery. Two

different models of healthcare delivery were described i.e. a shared care model and a nurse-led model, which were delivered in three different healthcare settings i.e. community, hospital and community, and hospital-based outpatient clinic. All three interventions were of short duration, however, length and intensity of follow-up from healthcare professionals varied. All three interventions incorporated an educational component, which addressed stroke knowledge, focussing specifically on the lifestyle risk factors for stroke and recurrent stroke, and the warning signs of TIA/stroke. However, the educational component of interventions differed in relation to approach, scope and focus.

Results

Approaches to measurement of outcomes and reporting of results differed to such an extent between the four papers that we have presented only meta-analyses indicating overall effects of the interventions.

Primary outcomes

Primary outcomes included lifestyle behaviour change and physiological outcomes.

Lifestyle behaviour change

The review focused on four lifestyle risk factors: tobacco use, physical activity, alcohol consumption and diet. The pooled results were significant and favoured intervention, thus indicating that the effectiveness of interventions designed to help participants initiate and maintain positive changes to lifestyle risk factor behaviour.

However, when the studies were considered individually, in terms of tobacco use, or smoking status, statistically significant behaviour change was not achieved in any of the studies (i.e. Joubert et al[32] Sit et al,[30] or Ellis et al[33]/McManus et al[31]). In Sit et al's[30] study the lack of effect is likely to be a reflection of the participants' previously 'healthy' lifestyle profiles, as the majority did not smoke prior to participation in the intervention. Lack of detail regarding the nature of the smoking cessation aspect of the interventions and whether, for example, participants' were referred to specialist

smoking cessation services prevents further interpretation of the results. There is a clear need for further evaluation with objective measurement.

With regards physical activity (walking for exercise), Joubert et al[32] reported a statistically significant improvement in the number of walks taken for exercise on a weekly basis, as a consequence of their intervention. Although participation in walking for exercise was not improved significantly following Sit et al's[30] intervention, it was maintained, whereas walking for exercise declined significantly in the control group. This may support the hypothesis that education combined with individualised goal setting is more likely to translate into behaviour change than providing education alone.[50]

Alcohol consumption was not reduced significantly following the interventions by Joubert et al[32] and Sit et al[30] although, in the case of Sit et al[30] this is likely to reflect the fact that, prior to participation, the majority of participants did not drink alcohol.

Only Sit et al[30] recorded dietary outcomes. They reported a significant reduction in the consumption of thick poultry bone soup and salt preserved food, common dietary elements in the South China region, although the statistical significance of this finding is questioned by our statistician. However, other studies have found that educational interventions impact positively on sustained dietary improvement (e.g. Greenlund et al[51]).

Physiological outcomes

Physiological outcomes include blood pressure, total cholesterol, diabetic management i.e. random blood glucose and mean HbA1c, and BMI. The pooled results were significant and favoured intervention.

In terms of blood pressure management, Joubert et al[32] reported a statistically significant reduction in systolic BP and an improvement in diastolic BP, which did not attain statistical significance. Ellis et al[33]/McManus et al[31] reported reductions in systolic and diastolic blood pressure which did not attain statistical significance. Controlling blood pressure to within recommended parameters may reduce risk of recurrent stroke by approximately 40%, therefore blood pressure control represents

an important secondary prevention outcome target.[52] Unfortunately, no detail is provided regarding the educational component of Joubert et al's[32] intervention to enable us to understand what might account for the partial success of the intervention in this respect.

In terms of total cholesterol, Joubert et al's[32] intervention demonstrated no significant differences between the groups. Both the intervention and control group cholesterol levels dropped below the parameters recommended in contemporary guidelines. However, Ellis et al[33]/McManus et al's[31] found no significant difference between their groups.

In terms of diabetic management, Ellis et al[33]/McManus et al's[31] report no significant differences between the groups in relation to random blood glucose levels and mean HbA1c levels. However, the analysis of the HbA1c data undertaken by our statistician, suggests that the difference was somewhat significant and favoured the control group (Table 14; Figure 2). It should, be noted, however, that this is likely to reflect a systematic bias linked to the attrition rate from baseline to 42 months.

In terms of BMI reduction, Joubert et al's[32] report a significant reduction in favour of the intervention. However, our results crossed the line of significance (Figure 2).

Secondary outcomes

Secondary outcomes included psychological outcomes, learning outcomes and recurrence of stroke and/or other vascular episodes. The pooled results are highly significant in favour of intervention; however the test for heterogeneity was also highly significant, which suggests large differences in the variables that have been pooled.

Psychological outcomes

Joubert et al[32] reported statistically significant changes in relation to quality of life. However, this was because participants in the intervention group maintained their quality of life scores, whilst the control group's scores reduced. This seems to indicate that, at 12 months post-stroke, intervention was successful in maintaining

but not improving quality of life whereas non-intervention resulted in worsening quality of life scores, thus indicating the perceived benefit of participation in such an intervention.

Learning outcomes

Stroke knowledge was measured in two studies.[30,32] Sit et al[30] measured stroke knowledge in relation to risk factors, warning signs and help seeking. According to our statistical analyses, a highly significant improvement was detected in relation to all three knowledge-related outcomes, particularly with regards knowledge of stroke warning signs and the need to take appropriate action. This is a potentially important result, as early identification of stroke or recurrent stroke is essential, as is taking appropriate action as urgently as possible.[53] It should be noted that all participants had received this information whilst still in hospital, prior to the intervention. However, the authors suggest that the success of the intervention in this respect demonstrates the importance of providing structured education following discharge, when this type of information is more compatible with patients' needs.[8,30,54] It is also notable that knowledge scores peaked at one week post intervention but fell away three months post-intervention. This may indicate a need for ongoing stroke knowledge education to be included as an element of long-term follow-up.[6]

Joubert et al[32] reported nine knowledge–related outcomes, however, the value of this data is limited as the outcomes were measured in terms of whether participants recalled receiving advice, rather than their ability to recall the content of any advice received. Of potential interest however, is the possibility of a direct association between education and behaviour change.[19] As noted above, Joubert et al[32] reported an association between cholesterol reduction and recall of having received advice regarding cholesterol management.

Recurrence of stroke and other vascular events

Only Ellis et al[33]/McManus et al[31] reported the recurrence of vascular events, and reported no statistically significant difference between intervention and control groups.

Limitations of the review

In terms of methodology, two limitations of the review are noted. Only papers published before August 2009 were included in the review, and searches of the grey were limited to two databases i.e. Conference Proceedings Citation Index - Science, and ProQuest Dissertation & Theses.

On occasion, the analyses conducted by our statistician indicated a significant result where none was indicated in the results reported by the authors of the papers included in the review. In other instances, the analyses conducted by our statistician indicated that a result was not significant, which had been reported as significant by the authors of the papers included in the review. However, as we did not have access to the raw data, in the results section we highlighted any such discrepancies and reported both sets of figures.

The studies were few in number and had only a small number of participants; therefore, the results reported here should be interpreted with caution.

Conclusions

Stroke secondary prevention lifestyle interventions are effective in terms of affecting positive change in relation to lifestyle behaviours, physiological outcomes and secondary outcomes. In particular, behavioural interventions were found by the authors to be effective in relation to increasing physical activity and improving dietary intake. In terms of physiological outcomes, interventions were found to be effective, particularly those aiming to reduce blood pressure. In relation to secondary outcomes, intervention was seen to exert a highly significant beneficial effect, in particular with regards improving quality of life, perceived self-health status, and stroke knowledge. There was insufficient evidence to determine the effect of intervention on incidence of stroke recurrence.

Implications for practice

Due to the lack of heterogeneity in the studies reviewed, the recommendations here are based on E2 level evidence (Appendix I).

Following stroke, clinicians should implement interventions to address behaviour change in relation to physical inactivity, excessive alcohol consumption and unhealthy diet, lifestyle behaviours which represent risk factors for recurrent stroke. Note: Whilst the evidence presented here does not show that intervention to change smoking behaviour, there is strong evidence in the wider tobacco literature to indicate that clinicians should encourage patients to quit smoking, and refer them to specialist smoking cessation services.

Following stroke, clinicians should implement interventions to address blood pressure management, cholesterol management, and BMI, physiological factors which represent lifestyle risk factors for recurrent stroke.

Note: Whilst the evidence presented here does not support intervention to improve diabetic control, there is strong evidence in the wider literature which indicates that clinicians should implement interventions that address diabetic management.

Following stroke, clinicians should implement behavioural/educational secondary prevention interventions to improve quality of life, self-perceived health status and stroke knowledge.

Implications for research

Further large scale, multi-site, well-designed RCTs, which use appropriate objective outcome measures, are required to determine a range of issues relating to the secondary prevention of stroke, including frequency/intensity of interventions, the most effective time for initiation of secondary prevention strategies, cost-effective models of delivery, determining whether such interventions are effective in supporting participants to sustain long-term changes to behaviour. In particular,

longitudinal studies are required that will to determine whether secondary prevention interventions effectively reduce the recurrence of stroke and other vascular events.

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Potential conflicts of interest

None

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Appendix I - Levels of Evidence: FAME scale

Levels of evidence	Feasibility F (1-4)	Appropriateness A (1-4)	Meaningfulness M (1-4)	Effectiveness E (1-4)
1.	Meta-synthesis of research with unequivocal synthesized findings.	Meta-synthesis of research with unequivocal synthesized findings.	Meta-synthesis of research with unequivocal synthesized findings.	Meta-analysis (with homogeneity) of experimental studies OR one or more large experimental studies with narrow confidence intervals.
2.	Meta-synthesis of research with credible synthesized findings.	Meta-synthesis of research with credible synthesized findings.	Meta-synthesis of research with credible synthesized findings.	One or more smaller RCTs with wider confidence intervals OR quasi-experimental studies (without randomization).
3.	a) Meta-synthesis of text/opinion with credible synthesized findings. b) One or more single research studies of high quality.	a) Meta-synthesis of text/opinion with credible synthesized findings. b) One or more single research studies of high quality.	a) Meta-synthesis of text/opinion with credible synthesized findings. b) One or more single research studies of high quality.	a) Cohort studies (with control groups) b) Case-controlled studies c) Observational studies
4.	Expert opinion.	Expert opinion.	Expert opinion.	Expert opinion or consensus.

Appendix II - Search strings

Search string used in AMED, ASSIA (1987 onwards), British Nursing Index and Archive 1985-2009, Embase (1980 t0 August 2009), Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R), and PsycINFO 1967-2009

SEARCH TOPIC	SEARCH STRINGS
STROKE	1. cerebrovascular disorders/ or exp basal ganglia cerebrovascular disease/ or exp brain ischemia/ or exp carotid artery diseases/ or exp intracranial arterial diseases/ or exp intracranial arteriovenous malformations/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ or stroke/ or exp brain infarction/ or vasospasm, intracranial/ or vertebral artery dissection/ 2. (stroke or poststroke or post-stroke or cerebrovasc$ or brain vasc$ or cerebral vasc$ or cva$ or apoplex$ or SAH).tw. 3. ((brain$ or cerebr$ or cerebell$ or intracran$ or intracerebral) adj5 (isch?emi$ or infarct$ or thrombo$ or emboli$ or occlus$)).tw. 4. ((brain$ or cerebr$ or cerebell$ or intracerebral or intracranial or subarachnoid) adj5 (haemorrhage$ or hemorrhage$ or haematoma$ or hematoma$ or bleed$)).tw. 5. 1 or 2 or 3 or 4
SECONDARY PREVENTION	6. health education.mp. or exp Health Education/ 7. health promotion.mp. or exp Health Promotion/ 8. health behavior.mp. or exp Health Behavior/ 9. secondary prevention.mp. or exp Secondary Prevention/ 10. counseling.mp. or exp Counseling/ 11. counsel$.mp. 12. (health adj5 (educat$ or program$ or promotion$ or behavio?r)).tw. 13. (patient adj5 (educat$ or program$)).tw. 14. 6 or 9 or 11 or 8 or 7 or 10 or 12 or 13 15. ((secondary or multifactor$) adj3 (prevention or intervention)).tw. 16. (risk adj3 factor$ adj5 (reduc$ or manag$ or intervent$)).tw. 17. (lifestyle adj3 (intervent$ or advice)).tw. 18. (life?style adj3 (intervention$ or advice or alter$ or educat$ or chang$)).tw. 19. (behavio?r$ adj3 chang$).tw. 20. (health?care adj3 advice).tw. 21. non?pharmacologic$.tw. 22. 15 or 16 or 17 or 18 or 19 or 21 or 20 23. 14 or 22
SECONDARY PREVENTION and STROKE	24. 5 and 23

Appendix III - JBI MAStARI Appraisal Instrument

Assessment for : Name of Assessment

Type: Primary
User: Default
Design: Randomised Control Tables / Psuedo-randomised Trial

	Criteria	Yes	No	Unclear
1)	Was the assignment to treatment groups truly random?	○	○	○
2)	Were participants blinded to treatment allocation?	○	○	○
3)	Was allocation to treatment groups concealed from the allocator?	○	○	○
4)	Were the outcomes of people who withdrew described and included in the analysis ?	○	○	○
5)	Were those assessing outcomes blind to the treatment allocation?	○	○	○
6)	Were the control and treatment groups comparable at entry?	○	○	○
7)	Were groups treated identically other than for the named interventions?	○	○	○
8)	Were outcomes measured in the same way for all groups?	○	○	○
9)	Were outcomes measured in a reliable way?	○	○	○
10)	Was appropriate statistical analysis used?	○	○	○

Include Yes
Reason

Update Cancel

Assessment for : Name of Assessment

Type: Primary
User: Default
Design: Comparable Cohort / Case Control Studies

	Criteria	Yes	No	Unclear
1)	Is sample representative of patients in the population as a whole?	○	○	○
2)	Are the patients at a similar point in the course of their condition/illness?	○	○	○
3)	Has bias been minimised in relation to selection of cases and of controls?	○	○	○
4)	Are confounding factors identified and strategies to deal with them stated?	○	○	○
5)	Are outcomes assessed using objective criteria?	○	○	○
6)	Was follow up carried out over a sufficient time period?	○	○	○
7)	Were the outcomes of people who withdrew described and included in the analysis?	○	○	○
8)	Were outcomes measured in a reliable way?	○	○	○
9)	Was appropriate statistical analysis used?	○	○	○

Include Yes
Reason

Update Cancel

Assessment for : Name of Assessment

Type: Primary
User: Default
Design: Descriptive / Case Series Studies

	Criteria	Yes	No	Unclear
1)	Was study based on a random or pseudo-random sample?	○	○	○
2)	Were the citeria for inclusion in the sample clearly defined?	○	○	○
3)	Were confounding factors identified and strategies to deal with them stated?	○	○	○
4)	Were outcomes assessed using objective criteria?	○	○	○
5)	If comparsons are being made, was there sufficient descriptions of the groups?	○	○	○
6)	Was follow up carried out over a sufficient time period?	○	○	○
7)	Were the outcomes of people who withdrew described and included in the analysis?	○	○	○
8)	Were outcomes measured in a reliable way?	○	○	○
9)	Was appropriate statistical analysis used?	○	○	○

Include Yes

Reason

Update Cancel

Appendix IV - Review-specific Data Extraction Instrument

Bibliographic details	
ID	
Author	
Year/country	
Title	
Citation	
Contact details	
Reference lists checked	yes/no

Study design		
Study Aim		
Sample		
Inclusion Criteria		
Exclusion Criteria		
	Intervention group	Control /comparison group
Sample size		
Recruitment Location		
Gender		
Age		
Ethnicity		
Socioeconomic		
Employment status		
Marital status		
Educational status		
Living Arrangements		
Stroke		
Definition		
Type		
Lesion location		
Severity		
Aphasia		
Cognitive impairment		
Affective disorders		
Co-morbidities		
Family history		

Intervention		
Theory		
Type		
Content		
Duration & frequency		
Who delivered the intervention?		
Did they have specific training?		
Intervention materials		
Structure		
Intervention Location		
Cost to participants		
Cost effectiveness		
Funder/provider		
Transport issues		
Family involvement		
Intervention for control group		
Outcomes		
	Intervention group	Control /comparison group
Measurement time points		
Who collected the data?		
Data collection tools		
Data collection methods		
Physiological variables measured		
Physiological results at baseline		
Physiological results at Time 1		
Psychological outcome measures		
Psychological results at baseline		
Psychological results at Time 1		
Knowledge: stroke warning signs		
Knowledge: risk factors		
Medication compliance		
Salt consumption		
Attitudes at Baseline		
Attitudes at Time 1		
Beliefs at baseline		
Beliefs at Time 1		

Appendix V: Key characteristics of included studies

Paper; Location; Design; Setting; Aim	Participants	Interventions	Outcomes
Paper: Joubert et al[18] **Location:** Melbourne, Australia **Design:** RCT **Setting:** Initiated in hospital, continued in primary care (shared care) **Aim:** To evaluate the effect of a multimodal programme designed to facilitate the implementation of recommended stroke secondary prevention strategies on risk factor modification, lifestyle changes, patient education and disability	**Inclusion criteria:** aged > 20years, admitted between 2000-2004, with TIA or complete stroke (cerebral infarction or parenchymal haemorrhage) as confirmed by CT scan **Exclusion criteria:** not returning to GP for management, discharged to nursing home, had serious comorbidities, non-English speaking, died whilst in hospital, 'too cognitively impaired', 'notably aphasic', lived more than 2 hours away by car. Suffered from subarachnoid haemorrhage or subdural haematoma **Intervention group** **Number:** 91 **Gender:** male: n=53 (58%) **Mean age:** 63.4 (SD 13.7) **Control group** **Number:** 95 **Gender:** male: n = 49 (52%) **Mean age**: 68.2 years (SD 12.7)	ICARUSS protocol targets 7 modifiable risk factors: BP, cholesterol, atrial fibrillation, BMI, smoking, alcohol intake, physical activity. Main intervention included early prescription of appropriate medications (anti-thrombotics, anticoagulants, diabetic treatment, anti-hypertensives and statins) by medical staff and promotion of lifestyle changes (smoking cessation, reduction in alcohol intake, maintenance of recommended BMI and deliberate physical activity) by the nurse co-ordinator. Early in-hospital initiation and sustained use of appropriate medical treatment and early commencement of education by the nurse co-ordinator regarding behaviour modification. Also, education to patients and carers regarding stroke risk factors and warning signs for stroke. A detailed risk-factor profile was recorded prior to discharge. **Follow up:** visits to GP at 2 weeks, 3 months, 6 months, 9 months and 12 months post stroke	**Primary outcome measures:** Systolic BP Diastolic BP **Secondary outcome measures:** Cholesterol Atrial fibrillation Smoking Alcohol intake Weight Physical activity (deliberate exercise walks per week) BMI **Other reported outcomes:** Stroke Risk Factor Knowledge (BP, cholesterol, smoking, alcohol, salt, physical activity, diabetes, symptoms, help seeking behaviour) Medication compliance AQol Rankin Barthel MMSE **Follow up:** 12 months post stroke

Paper; Location; Design; Setting; Aim	Participants	Interventions	Outcomes
Papers: Ellis et al[19] /McManus et al[17] (Note: these two papers reporting the same RCT study. Ellis et al[19] report baseline and 3-month follow up data, McManus et al[17] report 42-month follow up data) **Location:** Glasgow, Scotland **Design:** RCT **Setting:** Hospital–based nurse-led outpatient clinic **Aim**: To evaluate the effects of a brief nurse-led health education and counselling programme on risk factor control in post-stroke patients.	**Inclusion criteria:** clinical diagnosis of stroke, TIA or amaurosis fugax and had one or more risk factors i.e. high BP, history of current smoking, high cholesterol and/or diabetes **Exclusion criteria:** cognitive impairment (defined as an AMT <5 on screening) **Intervention group (baseline):** **Number:** 100 **Gender:** male: 54 (54%) **Mean age**: 64.3 (62.4-66.1, SD) **Control group (baseline):** **Number:** 105 **Gender:** male: 52 (50%) **Mean age**: 65.8 (64.0-67.5, SD) **Intervention group (at 42 month follow-up):** **Number:** 49 **Gender:** male: NR **Mean age**: NR **Control group (at 42 month follow-up):** **Number: 53** **Gender:** male: NR **Mean age**: NR	Clinic appointments incorporated education and counselling component delivered by a Stroke Nurse Specialist, who reviewed patients at monthly intervals for three months. Patients received individual advice on lifestyle changes, medication compliance, lifestyle issues (e.g. diet, exercise). Session lasted approximately 30 minutes, advice was tailored to patients'' circumstances and functional abilities. All verbal information was backed up by tailored written information. Personalised patient-held records detailing their risk factors and recommended risk factor targets were a key element of the intervention. Following the intervention, patients were discharged to the care of their GP and had no further input from the Stroke Nurse Specialist	**Primary outcome measures:** Systolic BP Diastolic BP Reported cigarette consumption Random blood glucose HbA1c **Secondary outcome measures:** Survival EuroQol perceived health status Geriatric Depression Score Stroke services satisfaction questionnaire **Follow-up:** 5 months (Ellis et al[19]); 42 months (SD 0.43) (McManus et al[17])

Paper; Location; Design; Setting; Aim	Participants	Interventions	Outcomes
Paper: Sit et al[16] **Location:** Hong Kong **Design:** Quasi-experimental i.e. group randomisation methods were used **Setting:** community based, nurse-led **Aim:** To determine the effectiveness of a community-based stroke prevention programme for patients with minor stroke, in improving stroke knowledge, improving in self health-monitoring practice, maintaining behavioural changes when adopting a healthy lifestyle for stroke prevention, and the reduction in physical parameters of stroke risk factors.	**Inclusion criteria:** aged <18 years, diagnosed with minor stroke, medically stable, independent in activities of daily living, cognitively intact and able to communicate in Cantonese, currently living in the community, and currently not receiving or pending surgical treatment. **Exclusion criteria:** congenital vascular abnormality e.g. arteriovenous malformation, haemorrhagic stroke, stroke-like symptoms from other causes **Intervention group:** **Number:** 107 **Gender:** male: n = 55 (52%) **Mean age:** 62.83 years (10.25) **Control group:** **Number:** 83 **Gender:** male: n = 50 (60%) **Mean age:** 64.02 years (12.03)	Structured classes and group work; 8 two-hour sessions held once a week; 10-12 participants per class. The content of the programme was developed according to national guidelines and findings from local studies on stroke survivors' and caregivers' information needs. Each session opened with a 15 minutes experience sharing. The programme focused on individual goal setting and action plans and self-care/self-health monitoring. Adult learning strategies were used e.g. participants selected the risk behaviours on which they wanted to focus, addressed them one at a time, set practical short-term goals, had a written record of the goals , and discussed these with the facilitator and fellow participants at the end of each session. Participants practiced the learned skills and implemented their action plan at home before the next session. In the subsequent session, participants reported whether their goals had been attained. Feedback and experience sharing assisted reinforcement and reflection.	**Primary outcome measures:** Stroke knowledge Self health-monitoring practice Medication compliance Reported cigarette consumption Reported alcohol consumption Walking (walking for exercise) Reported dietary intake **Other reported outcomes:** BP self-monitoring log **Follow up:** 3 months post intervention completion

Appendix VI: Excluded Studies

Paper	Reason for exclusion			
	Poor quality	Not behaviour change	Insufficient data	Other
Anon. 2003. Stroke and exercise. *SportEX Health,* 17, 14-14.				Patient advice leaflet
Ada, L., Dean, C.M., Hall, J.M., Bampton, J., Crompton, S., 2003. A treadmill and overground walking program improves walking in persons residing in the community after stroke: a placebo. *Archives of Physical Medicine and Rehabilitation,* 84, 1486-1491.				Functional recovery
Altman, J., Kornhuber, A.W., Kornhuber, H.H., 1987. Stroke: cardiovascular risk factors and the quantitative effects of dietary treatment on them. *European Neurology,* 26(2), 90-99.	✓			
Banet, G.A., Felchlia, M.A., 1997. The potential utility of a shared medical record in a "first-time" stroke population. *Journal of Vascular Nursing,* 15(1), 29-33.	✓			
Bastien, M., Kornerbitensky, N., Lalonde, S., Lebrun, N., Matte, D., 1998. A health and leisure program for community-dwelling individuals with stroke: A pilot study. *Canadian Journal of Rehabilitation*, 12(1), 7-14.	✓			
California Acute Stroke Pilot Registry Investigators, 2005. The impact of standardized stroke orders on adherence to best practices. *Neurology,* **65**(3), 360-365.				Adherence to standards and guidelines
Centers for Disease Control and Prevention, 1999. Physician advice and individual behaviors about cardiovascular disease risk reduction in seven states and Puerto Rico, 1997. *Morbidity & Mortality Weekly Report,* 47, 91-95.				Not stroke specific
Centers for Disease Control and Prevention, 1998. Missed opportunities in preventive counseling for cardiovascular disease, United States, 1998. *Morbidity & Mortality Weekly Report,* 48, 74-77.				Not stroke specific
Chanruengvanich, W., Kasemkitwattana, S., Charoenyooth, C., Towanabut, S., Pongurgsorn, C., 2006. RCT: self-regulated exercise program in transient ischemic attack and minor stroke patients. *Thai Journal of Nursing Research,* 10(3), 165-179.				Unable to locate
Cheng, E., Chen, A., Vassar, S., Lee, M., Cohen, S.N., Vickrey, B., 2006. Comparison of secondary prevention care after myocardial infarction and stroke. *Cerebrovascular Diseases,* 21(4), 235-241.				Adherence to guidelines

Duncan, P., Richards, L., Wallace, D., Stoker-Yates, J., Pohl, P., Luchies, C. et al., 1998. A randomized, controlled pilot study of a home-based exercise program for individuals with mild and moderate stroke. *Stroke,* 29(10), 2055-2060.				Functional recovery
Eng, J.J., Chu, K.S., Kim, C.M., Dawson, A.S., Carswell, A., Hepburn, K.E., 2003. A community-based group exercise program for persons with chronic stroke. *Medicine & Science in Sports & Exercise,* 35(8), 1271-1278.				Functional recovery
Fu, D., Fu, H., Mcgowan, P., Shen, Y.E., Zhu, L., Yang, H., Mao, J., Zhu, S., Ding, Y., Wei, Z., 2003. Implementation and quantitative evaluation of chronic disease self-management programme in Shanghai, China: randomized controlled trial. *Bulletin of the World Health Organization,* 81(3), 174-182.				Not stroke specific
Furtado, S., Coelho, C.M., Gonçalves, I., Sampaio, R.F., Mancini, M.C., 2006. Adherence of individuals with stroke to a home-based exercise program [Portuguese]. *Fisioterapia em Movimento,* 19(3), 41-46.				Unable to locate
Greenlund, K.J., Giles, W.H., Keenan, N.L., Croft, J.B., Mensah, G.A., 2002. Physician advice, patient actions, and health-related quality of life in secondary prevention of stroke through diet and exercise. *Stroke*, 33(2), 565-570.	✓			
Harrington, R., Taylor, G., Duggan Á, Reed, M., Wood, V., 2007. The evaluation of a community-based stroke scheme. *Disability & Rehabilitation,* 29(20-21), 1636-1636.				Improving fitness
Herderschee, D., Hijdra, A., Algra, A., Koudstaal, P.J., Kappelle, L.J., Van Gijn, J., 1992. Silent stroke in patients with transient ischemic attack or minor ischemic stroke. The Dutch TIA Trial Study Group. *Stroke,* 23(9), 1220-1224.	✓			
Huijbregts, M.P., Myers, A.M., Streiner, D., Teasell, R., 2008. Implementation, process, and preliminary outcome evaluation of two community programs for persons with stroke and their care partners. *Topics in Stroke Rehabilitation,* 15(5), 503-520.	✓			
Jeong, S., Kim, M.T., 2007. Effects of a theory-driven music and movement program for stroke survivors in a community setting. *Applied Nursing Research,* 20(3), 125-131.				Functional recovery
Kang, H.S., Kim, W.O., Kim, J.W., Wang, M.J., Cho, J.H., 2004. [Effect of East-West Self-help Group program for rehabilitation of post stroke clients]. *Daehan Ganho Haghoeji,* 34(7), 1351-1361.				Did not meet inclusion criteria
Kaplan, S., Weiss, W., 2006. Results of a 6 week education-based group exercise class for individuals with stroke... Platforms, thematic posters, and posters for CSM 2007. *Journal of Neurologic Physical Therapy*, 30(4), 216.	✓		Poster abstract	

Lai, J.C., Woo, J., Hui, E., Chan, W.M., 2004. Telerehabilitation - a new model for community-based stroke rehabilitation. *Journal of Telemedicine & Telecare*, 10(4), 199-205.	✓			
Langhammer, B., Lindmark, B., Stanghelle, J.K., 2007. Stroke patients and long-term training: is it worthwhile? A randomized comparison of two different training strategies after rehabilitation. *Clinical Rehabilitation,* 21(6), 495-510.				Functional recovery
Lapcevic, M., Vukovic, M., Dimitrijevic, I., Kalezic, N., Ristic, J., 2007. [The effect of medicamentous and non-medicamentous therapy on lowering risk factors for cardiovascular and cerebrovascular episodes in an interventional study]. *Srpski arhiv za celokupno lekarstvo,* 135(9-10), 554-561.				Not specific to stroke
Lee, S.L., Lui, M.H., Mackenzie, A.E., 2005. The impact of a multidisciplinary stroke education programme on Chinese family carers. *Journal of Interprofessional Care,* 19(4), 406-407.	✓			
Lennon, O., Blake, C., 2009. Cardiac rehabilitation adapted to transient ischaemic attack and stroke (CRAFTS): a randomised controlled trial. *BMC Neurology,* 9, 9.				Intervention development not evaluation
Lennon, O., Carey, A., Gaffney, N., Stephenson, J., Blake, C., 2008. A pilot randomized controlled trial to evaluate the benefit of the cardiac rehabilitation paradigm for the non-acute ischaemic stroke population. *Clinical Rehabilitation*, 22(2), 125-133.		✓		
Ma, R.H., Wang, Y.J., Wang, C.X., Zhao, X.Q., Wang, Y.L., Xu, M.J., Wei, M., Li, Y., Zhang, Z., Zhang, W.W., Wang, L., Lin, L., Li, H.T., Zheng, T., Wang, X.W., Li, J.J., Lu, Y., Qi, D., 2008. [A survey on cerebral infarction/transient ischemic attack inpatients compliance with secondary stroke prevention and follow-up 90 days]. *Chung-Hua i Hsueh Tsa Chih [Chinese Medical Journal],* 88(37), 2618-2622.				Adherence to guidelines
Maeshima, S., Moriwaki, H., Ozaki, F., Hashio, M., Kusuyama, H., Sasaki, Y., et al., 2001. Early rehabilitation program for hemiplegic stroke patients: Useful training conducted by patient families, W. PEEK and G.J. LANKHORST, eds. In: *1st World Congress of the International Society of Physical and Rehabilitation Medicine, 2001.* 537-541.				Functional recovery
Martin, B.J., Yip, B., Hearty, M., Marletta, S., Hill, R., 2002. Outcome, functional recovery and unmet needs following acute stroke. Experience of patient follow up at 6 to 9 months in a newly established stroke service. *Scottish Medical Journal,* 47(6), 136-137.				No control group

Mead, G.E., Greig, C.A., Cunningham, I., Lewis, S.J., Dinan, S., Saunders, D.H., Fitzsimons, C., Young, A., 2007. Stroke: a randomized trial of exercise or relaxation. *Journal of the American Geriatrics Society,* 55(6), 892-899.				Endurance fitness
Middleton, S., Donnelly, N., Harris, J., Ward, J., 2005. Nursing intervention after carotid endarterectomy: a randomized trial of Co-ordinated Care Post-Discharge (CCPD). *Journal of advanced nursing,* 52(3), 250-261.				Not stroke specific
Nir, Z., Zolotogorsky, Z., Sugarman, H., 2004. Structured nursing intervention versus routine rehabilitation after stroke. *American Journal of Physical Medicine & Rehabilitation,* 83(7), 522-529.			✓	
Olney, S.J., Nymark, J., Brouwer, B., Culham, E., Day, A., Heard, J., Henderson, M., Parvataneni, K., 2006. A randomized controlled trial of supervised versus unsupervised exercise programs for ambulatory stroke survivors. *Stroke,* **37**(2), 476				Functional improvement
O'Mahony, P.G., Rodgers, H., Thomson, R.G., Dobson, R., James, O.F., 1997. Satisfaction with information and advice received by stroke patients. *Clinical Rehabilitation,* 11(1), 68-72.				Survey re satisfaction with services
Ovbiagele, B., Saver, J.L., Fredieu, A., Suzuki, S., Selco, S., Rajajee, V., Mcnair, N., Razinia, T., Kidwell, C.S., 2004. In-hospital initiation of secondary stroke prevention therapies yields high rates of adherence at follow-up. *Stroke,* 35(12), 2879-2883.	✓			
Pang, M.Y., Harris, J.E., Eng, J.J., 2006. A community-based upper-extremity group exercise program improves motor function and performance of functional activities in chronic stroke: a randomized controlled trial. *Archives of Physical Medicine & Rehabilitation,* 87(1), 1-9.				Functional recovery
Pang, M.Y., Eng, J.J., Dawson, A.S., Mckay, H.A., Harris, J.E., 2005. A Community A Community-Based Fitness and Mobility Exercise Program for Older Adults with Chronic Stroke: A Randomized, Controlled Trial. *Journal of the American Geriatrics Society,* 53(10), 1667-1674.		✓		
Qureshi, A.I., Suri, M.F., Guterman, L.R., Hopkins, L.N., 2001. Ineffective secondary prevention in survivors of cardiovascular events in the US population: report from the Third National Health and Nutrition Examination Survey. *Archives of Internal Medicine,* 161(13), 1621-1628.				Adherence to guidelines

Rahiman, A., Saver, J.L., Porter, V., Buxton, W., Mcnair, N., Razinia, T., Ovbiagele, B., 2008. In-hospital initiation of secondary stroke prevention therapies yields high rates of adherence at follow-up. *Stroke,* 35(12), 2879-2883.			✓	
Rausch, M., Turkoski, B., 1999. Developing realistic treatment standards in today's economic climate: stroke survivor education. *Journal of Advanced Nursing,* 30(2), 329-334.	✓			
Resnick, B., Michael, K., Shaughnessy, M., Nahm, E.S., Kobunek, S., Sorkin, J., Orwig, D., Goldberg, A., Macko, R.F., 2008. Inflated perceptions of physical activity after stroke: pairing self-report with physiologic measures. *Journal of Physical Activity & Health,* 5(2), 308-318.				Not a behavioural intervention
Rimmer, J.H., Rauworth, A.E., Wang, E.C., Nicola, T.L., Hill, B., 2009. A preliminary study to examine the effects of aerobic and therapeutic (nonaerobic) exercise on cardiorespiratory fitness and coronary risk reduction in stroke survivors. *Archives of Physical Medicine & Rehabilitation,* 90(3), 407-412.		✓		
Rimmer, J.H., Riley, B., Creviston, T., Nicola, T., 2000. Exercise training in a predominantly African-American group of stroke survivors. *Medicine & Science in Sports & Exercise,* 32(12), 1990-1996.	✓			
Rimmer, J.H., Braunschweig, C., Silverman, K., Riley, B., Creviston, T., Nicola, T., 2000. Effects of a short-term health promotion intervention for a predominantly African-American group of stroke survivors. *American Journal of Preventive Medicine,* 18(4), 332-338.	✓			
Robinson, F., 2005. Practice Nurse of the Year projects 2004. *Practice Nurse,* 29(2), 12-15.				Not a behavioural intervention
Rodriguez, C.J., Sacco, R.L., Sciacca, R.R., Boden-Albala, B., Homma, S., Di Tullio, M.R., 2002. Physical activity attenuates the effect of increased left ventricular mass on the risk of ischemic stroke: The Northern Manhattan Stroke Study. *Journal of the American College of Cardiology,* 39(9), 1482-1488.				Effects of physical activity on left ventricular mass
Studenski, S., Duncan, P.W., Perera, S., Reker, D., Lai, S.M., Richards, L., 2005. Daily functioning and quality of life in a randomized controlled trial of therapeutic exercise for subacute stroke survivors. *Stroke (00392499),* 36(8), 1764-1770.				Functional recovery

Sue-Min Lai, Studenski, S., Richards, L., Perera, S., Reker, D., Rigler, S., Duncan, P.W., 2006. Therapeutic exercise and depressive symptoms after stroke. *Journal of the American Geriatrics Society,* 54(2), 240-247.				Exercise to alleviate symptoms of depression
Tang, A., Sibley, K.M., Thomas, S.G., Bayley, M.T., Richardson, D., Mcilroy, W.E., Brooks, D., 2009. Effects of an Aerobic Exercise Program on Aerobic Capacity, Spatiotemporal Gait Parameters, and Functional Capacity in Subacute Stroke, *Neurorehabilitation and Neural Repair; 15th WCPT World Congress of Physical Therapy,* 2007; MAY 2009. 398-406.				Effects of aerobic training on functional recovery/endurance
Taskinen, P., 1999. The development of health enhancing exercise groups adapted for hemiplegic patients: A pilot study. *NeuroRehabilitation,* 13(1), 35-43.	✓			
Teixeira, L.F., 1999. *The impact of a program of muscle strengthening and physical conditioning on impairment and disability in chronic stroke subjects*. *Archives of Physical Medical Rehabilitation,* 8, 1211-1218.				Functional recovery
Wiesemann, A., Engeser, P., Reichert, K., Mollien, P., Schach, S., Scheidt, R., 2004. [Quality of primary medical care after in-patient stroke rehabilitation]. *Gesundheitswesen,* 66(1), 29-36.				Adherence to guidelines